



Diagnostics

Elecsys[®] 2010

Operator's Manual

Software Version 06.03

Revision History

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Edition Notice**Elecsys 2010 Operator's Manual**

This manual is for users of the Elecsys 2010 analyzer.

Every effort has been made to ensure that all the information contained in this manual is correct at the time of printing. However, Roche Diagnostics GmbH reserves the right to make any changes necessary without notice as part of ongoing product development.

Any customer modification to the instrument will render the warranty or service agreement null and void. For warranty conditions, refer to the analyzer purchase agreement. Contact your local Roche Diagnostics representative for further information.

Software updates are done by Roche Diagnostics representatives.

Intended use

This operator's manual is intended to be used as an instructional aid in the performance of tasks related to the operation and general maintenance of the instrument. The manual contains detailed descriptions of instrument features and general operational concepts, specifications, theory of operation, function and use of controls, operating techniques, emergency procedures, product labeling and maintenance procedures.

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Instrument approvals

Our instruments meet the protection requirements laid down in IVD Directive 98/97/EC and the European Standard prEN591. Furthermore, our instruments are manufactured and tested according to the international standards EN 61010-1/ IEC 61010-2-081/ IEC 61010-2-101.

Compliance is demonstrated by the following marks:



Complies with the IVD directive 98/79/EC.



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Preface

The Roche Diagnostics Elecsys 2010 Immunoassay System is a fully automated, random access, software-controlled system for immunoassay analysis. It is available as both a disk system and a rack system. The differences between the two configurations are detailed throughout this operator's manual.

The Elecsys 2010 analyzer was designed for both quantitative and qualitative in vitro determinations using a wide variety of tests. Both disk and rack systems have a throughput per hour of approximately 86 tests.

The Elecsys 2010 analyzer can be placed on a bench top, thus saving space in the laboratory environment. Handling of the system is easy; potential for manual errors is reduced to a minimum. All assay reagent, calibrator and control information is automatically entered into the software by bar codes.

The system consists of the analyzer, which performs all functions required for fully automated sample and assay processing, and a control unit, which controls the analyzer through the user software. This entirely automated process begins with the recording of patient samples - provided that they are in bar code-labeled tubes - up to the electrochemiluminescent detection and results transmission.

Data transmission to and from the analyzer, results evaluation, documentation, and quality control are performed automatically by the software. Furthermore, the software is responsible for the management of data between a connected laboratory information system (LIS) and the 2010 analyzer. Several Elecsys analyzers can be centrally controlled when integrated with the Laboratory System Manager (LSM) designed by Roche Diagnostics (note that the Laboratory System Manager (LSM) is not available to US customers).

An outstanding feature of the analyzer system is the touchscreen and easy to use software.



- Keep this manual in a safe place to ensure that it is not damaged and remains available for use.
- This Operator's Manual should be easily accessible at all times.

How to use this manual

The general table of contents at the beginning of each guide and the subject index located in the back of the guide, provide points of quick correlation for cross referencing. Pictorials are repeated as necessary to minimize page flipping and references are made between sections to point out specific guide information. You should not operate the instrument until you are thoroughly familiar with the information in this manual.

The manual is divided into the following four guides:

Reference Guide (Part A):

This book provides general information about Roche Diagnostics (e.g., ordering reagents and contacting technical support), an introduction to the analyzer, instrument specifications, precautions and warnings, mechanical and chemistry methodology theory.

Software Guide (Part B):

This book describes in detail the software on the analyzer. A basic organisation as well as detailed menu/screen displays are provided. Reports from the analyzer are also found in this book.

User's Guide (Part C):

This book contains general troubleshooting, data and instrument alarms, maintenance and a spare parts list.

Tutorial Guide (Part D):

This book provides a basic overview of the system, daily operational procedures and a "How to..." section (i.e., instructions on most tasks the average operator is required to perform).

The manual also contains a Glossary (Part E) and an Index (Part F).

Where to find Information:

Interactive CD-ROM

The Interactive CD-ROM available with your manual contains five language versions of the information in this manual in PDF file format (English, French, Italian, Spanish and Portuguese). You will need to have Adobe Acrobat Reader installed on your PC to be able to view and print the PDF files. If you order the short guide you will also receive the CD-ROM.

Short Guide

Also available with this manual is the Short Guide. This small document is designed to complement your operator's manual. The Short Guide tells you exactly what is necessary to operate the analyzer, without the level of detail found in the Tutorial Guide. Please refer to the Tutorial Guide of your operator's manual for additional operational details.

Customer Information:

Customer Training

Contact your local Roche service representative for questions regarding Elecsys 2010 analyzer training.

Test Specific Information

Information specific to a particular chemistry test can be found in the chemistry package insert and/or product information for that method (note that product information sheets are not available in the USA).

Contact Customer Service

Contact your local Roche service representative for further information regarding the Elecsys 2010 analyzer service agreement.

Ordering Information

Replacement parts, consumable materials, reagents, calibrators and controls should be ordered from Roche Diagnostics. When ordering, please use the Roche Diagnostics catalog number and reference name for each item. Contact your local Roche service representative for the detailed ordering list.






If you order the Short Guide you will also receive an interactive CD-ROM containing five language versions of the information in this manual in PDF file format.

Conventions used in this manual

Visual cues are used to help locate and interpret information in this manual quickly. This section explains formatting conventions used in the manual.

Symbols

The following symbols are used:

Symbol	Used for
•	Bullet
	Note
	Caution
	Warning
	Disk system specific
	Rack system specific

**Elecsys 2010
Reference Guide**

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This manual describes the Software Version 06-01 of 04/2002.

This manual was created by the Roche Diagnostics Technical Publications Department. Questions/ comments regarding the content of this manual can be directed to your local Roche Diagnostics representative, or to:

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1. Introduction

1.1 Introduction

The Reference Guide is part of the Elecsys 2010 Operator's Manual, which also consists of the Software Guide, User's Guide, Tutorial Guide and the Short Guide.

The Reference Guide gives a comprehensive overview of the Elecsys 2010 analyzer. Furthermore, this guide gives background information on all system-specific topics that are not necessarily part of the daily routine, but give valuable information on the function of the entire system.

The Reference Guide covers all topics relating to the functionality of the instrument and the technical data. In addition, it contains descriptions of the measuring methods on which the tests are based.

The Reference Guide also describes in detail the safety precautions that must be heeded while working with the 2010 system.

1.2 The Elecsys 2010 Immunoassay System

The Roche Diagnostics Elecsys 2010 Immunoassay System is a fully automated, random access, software-controlled system for immunoassay analysis. It is available as both a disk system and a rack system. The differences between the two configurations are detailed throughout this operator's manual.



Elecsys 2010 disk system



Elecsys 2010 rack system

The Elecsys 2010 was designed for both quantitative and qualitative in vitro determinations using a wide variety of tests. Both disk and rack systems have a throughput per hour of approximately 86 tests.

The Elecsys 2010 analyzer can be placed on a bench top, thus saving space in the laboratory environment. Handling of the system is easy; potential for manual errors is reduced to a minimum. All assay reagent, calibrator and control information is automatically entered into the software by bar codes.

The system consists of the analyzer, which performs all functions required for fully automated sample and assay processing, and a control unit, which controls the analyzer through the user software. This entirely automated process begins with the recording of patient samples - provided that they are in bar code-labeled tubes - up to the electrochemiluminescent detection and results transmission.

Data transmission to and from the analyzer, results evaluation, documentation, and quality control are performed automatically by the software. Furthermore, the software is responsible for the management of data between a connected laboratory information system (LIS) and the 2010. Several Elecsys analyzers can be centrally controlled when integrated with the Laboratory System Manager (LSM) designed by Roche Diagnostics.

An outstanding feature of the analyzer system is the touchscreen and easy to use software. The advantages of the system include:

- Easy operation via touchscreen, very few manual entries required.
- Integrated bar code concept improves convenience and workflow. Manual entry of individual sample identifications is not required, if bar code-labeled tubes are used. Sample racks (on the rack system), reagent packs, calibrator and control vials (also bar code-labeled) are also read automatically.
- Automatic entry of test applications. Transfer of test parameters to the system via the reagent bar code label speeds installation of new assays.
- Real time monitoring of the analyzer allows the system to run unattended. The operator is immediately notified of any problems.
- Continuous access to samples avoids interruption of routine testing while ensuring that results will be available as quickly as possible.
- STAT samples are prioritized and processed first.
- Reagents are kept at a constant temperature (20 ± 3 °C) on the analyzer, allowing on-analyzer storage.

1.3 General Overview

The Roche Diagnostics Elecsys® 2010 Immunoassay System is an automated, random access, multichannel analyzer for immunological tests, intended for in vitro quantitative or qualitative determination of a wide range of analytes. The analyzer is specially designed for performing assays utilizing electrochemiluminescent (ECL) technology and is marketed by Roche Diagnostics.

Packaged with your analyzer, you will receive an:

- accessory kit
- installation kit

After your instrument is installed, the following consumable materials should be ordered as necessary from Roche Diagnostics:

- | | |
|---------------------------------|----------------------------------|
| ● reagents | ● assay cups |
| ● calibrator sets | ● assay tips |
| ● CalCheck kits (USA only) | ● CalSet Vials |
| ● Elecsys ProCell | (empty calibrator/control vials) |
| ● Elecsys CleanCell | ● Clean-Liners |
| ● Elecsys BlankCell | ● printer paper |
| ● control material | ● printer ribbon |
| ● SysWash | ● SysClean |
| ● Racks (for rack systems only) | |

General

This operator's manual is intended to be used as an instructional aid in the performance of tasks related to the operation and general maintenance of the instrument. The manual contains detailed descriptions of instrument features and general operational concepts, specifications, theory of operation, function and use of controls, operating techniques, emergency procedures, product labeling and maintenance procedures.

Warranty

For warranty conditions, refer to the analyzer purchase agreement. Contact your local Roche Diagnostics representative for further information.

Using the Operator's Manual

You should not operate the instrument until you are thoroughly familiar with the information in this manual.

The manual is divided into the following four guides:

- **Reference Guide:** This book provides general information about Roche Diagnostics (e.g., ordering reagents and contacting technical support), an introduction to the analyzer, instrument specifications, precautions and warnings, mechanical and chemistry methodology theory.
- **Software Guide:** This book describes in detail the software on the analyzer. A basic organization and navigation, as well as detailed menu/screen displays are provided. Reports available from the analyzer are also found in this book.
- **User's Guide:** This book contains general troubleshooting, data and instrument alarms, maintenance and a spare parts list.
- **Tutorial Guide:** This book provides a basic overview of the system, daily operational procedures and a "How to..." section (i.e., instructions on most tasks the average operator is required to perform).

Also included with the manual is the Short Guide. This small document is designed to complement your operator's manual. The Short Guide tells you exactly what is necessary to operate the analyzer, without the level of detail found in the Tutorial Guide. Please refer to the Tutorial Guide of your operator's manual for additional operational details.

Manual Set-up

The general table of contents at the beginning of each guide and the subject index located in the back of the guide, provide points of quick correlation for cross referencing. Pictorials are repeated as necessary to minimize page flipping and references are made between sections to point out specific guide information.

Analyzer Installation

Installation is performed by a Roche Diagnostics representative. The customer is responsible for providing the necessary facilities as detailed in Section 2.7, Technical Data.

Service

Contact your local Roche Diagnostics representative for further information regarding the Elecsys 2010 analyzer service agreement.

Customer Training

Contact your local Roche Diagnostics representative for questions regarding Elecsys 2010 analyzer training.

Test Specific Information

Information specific to a particular chemistry test can be found in the chemistry package insert and/or product information for that method.

Ordering Information

Replacement parts, consumable materials, reagents, calibrators and controls should be ordered as necessary from Roche Diagnostics. When ordering, please use the Roche Diagnostics catalog number and reference name for each item.

1.4 Product Labeling

Elecsys reagent packs have a special 2D (two dimensional) bar code. This allows fully automatic registration and management of reagent information. Manual entry or additional monitoring is not necessary. The ready-to-use, liquid reagents are loaded into one of the 18 positions on the reagent disk. Reagents are available for analysis after their bar codes are scanned.

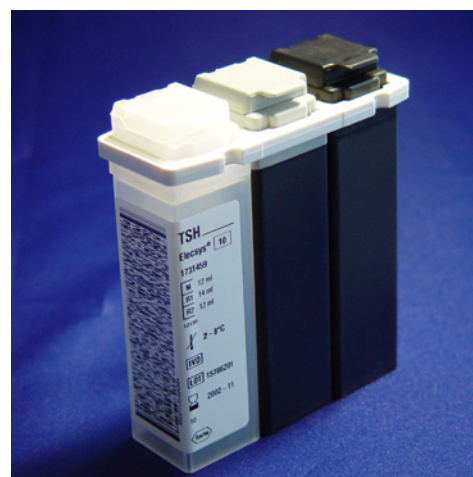
The handling of calibrators and Roche Diagnostics controls corresponds to that of reagents. Most calibrators are ready-to-use. Lyophilized controls and some calibrators must be prepared and transferred into the appropriate container. For quantitative assays, calibrator and control information is stored on 2D bar code cards (refer to subsection, Calibrator and Control Bar Code Cards). For qualitative assays, all information necessary for calibration is encoded on the bar-coded bottle labels.

Reagent Kits (Reagent Packs)

The photo shows an example of the reagent pack used on the Elecsys 2010 analyzer. Each reagent pack is a ready-to-use single unit. A reagent pack consists of three bottles:

- a white bottle with a white or transparent lid containing the suspended paramagnetic microparticles, that act as the carrier material of the ruthenium-labeled complex during measurement
- a black bottle with a gray lid containing R1
- a black bottle with a black lid containing R2.

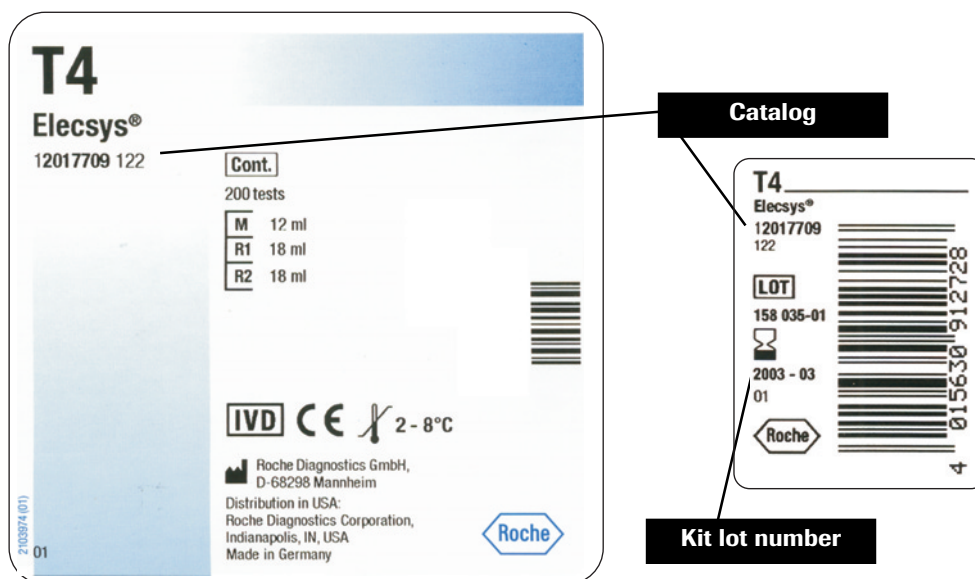
The reagent pack and reagent disk are keyed so reagents cannot be placed incorrectly on the analyzer.



Elecsys reagent pack

Reagent Kit Box Labels

The large label contains the intended use statement, storage temperature, contents and catalog number of the kit. The smaller side box label contains the lot and expiration date of the kit, as well as a bar code number. This bar code number is used for tracking purposes and is not used by the analyzer.



Elecsys reagent box labels (actual size)

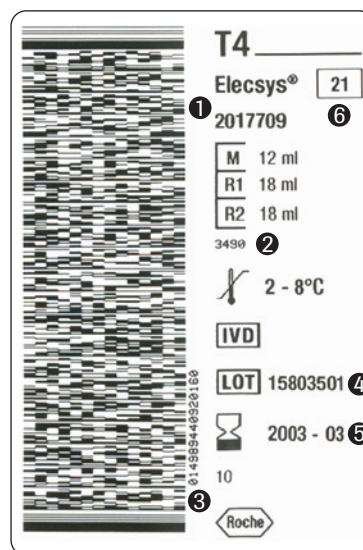
Reagent Bar Code Label

Reagent packs have a bar code label that contains information required to run the assay on the analyzer. This information includes, but is not limited to:

- test number
- lot number
- master calibration curve parameters (e.g., Rodbard parameters)
- instrument settings
- calibrator lot numbers and assigned values
- expiration date
- calibration frequency

The following information can be identified on each reagent bar code label:

- 1 kit catalog number
- 2 reagent pack number
- 3 reagent bar code number
- 4 kit lot number
- 5 expiration date
- 6 code for generation number



T4 reagent bar code label
(actual size)

The reagent bar code labels are in a unique format. The symbology utilizes portable data files (PDF) and is called PDF417. Traditional linear bar codes serve as a link to a database that contains the appropriate information. PDF417 is a two-dimensional, stacked bar code that contains an entire data record. The large amount of data that can be encoded allows all instrument settings to be included, as well as the master calibration curve and additional information for the assay. It is from this master calibration curve and from the operator 2-point calibration that the analyzer derives the update of the master calibration curve. For further information, refer to Chapter 6, Calibration.

"Every PDF417 symbol (bar code) contains two error detection codewords that are used like the check digit in linear bar code symbologies to detect decode errors and verify that all data have been read and decoded accurately. Additionally, PDF417 provides error correction in the event that portions of the symbol have been damaged, destroyed or are unreadable." ¹

It is a combination of this error detection and error correction that ensures a reliable bar code. There should only be exceptional cases when bar codes are so badly damaged that they cannot be read by the analyzer. If the bar code cannot be read and the reagent lot has been previously used by the analyzer, the 15-digit number found on the reagent bar code label can be manually entered into the software.

Package Insert

Each reagent kit comes with a package insert. This insert contains information required to perform the assay. Detailed information is contained in the product information sheet supplied separately.

Product Information Sheet

Each assay applied to this analyzer has a product information sheet that provides general information about the assay. Data contained in the product information sheet is more detailed than what is in the package insert. Instrument settings are encoded in reagent bar codes and not entered by the operator. This type of information such as sample volume, reagent volume, etc. is found in the Overview section of the product information sheet.

The product information sheets, which comply with the standards set by the following instructions: NCCLS, CLIA and HCFA, can be ordered from Roche Diagnostics as required.

1. Itkin S, Martell J. A PDF417 Primer: A Guide to Understanding Second Generation Bar Codes and Portable Data Files. Bohemia, NY: Symbol Technologies, Inc; 1992:17-18.

Calibrator Kits

For most tests, calibrators for the Elecsys reagents come packaged separately (e.g., Elecsys Troponin-T CalSet). Each kit contains bar coded calibrator vials. Most calibrators are in a ready to use liquid form and require no further action other than to place them on the sample disk or rack when a calibration is necessary.

A few of the calibrators are lyophilized in glass bottles and must be reconstituted before being transferred into plastic bar code-labeled vials. (Empty bar code-labeled vials are packaged in these kits with lyophilized calibrators.) Reconstituted calibrators can be stored in the plastic vials after transfer.

Calibrators also have color-coded caps to assist you in identification. A white cap is a level 1 calibrator and a black cap is a level 2 calibrator.

Calibrator bar code cards come packed in each calibrator kit. These cards are described in more detail in the next section.



TSH calibrator kit

Calibrator Bar Code Cards

Each calibrator kit comes with bar code cards. These cards are also in the PDF417 format and must be used in conjunction with the corresponding calibrators. Information encoded in the calibrator bar code cards includes, but is not limited to:

- test number
- calibrator lot number
- lot identifier to calibrator bar code labels
- what calibrators are to be used and their number of determinations
- target or assigned values
- expiration date

Roche Diagnostics produces a factory master calibration for each calibration lot. The results are encoded into the corresponding reagent bar code. Scan the new bar code card when a new lot of calibrator is used.

Calibrator Bar Code Labels

Each calibrator bottle has a traditional linear bar code label that contains an identifier to link it to information encoded in the reagent bar code label and the calibrator bar code card.



Calibrator bottle bar code labels

Control Kits

For most tests, controls for the Elecsys reagents come packaged separately (e.g., Elecsys PreciControl Universal). Each kit contains bar coded control vials ready-for-use on the analyzer.

A few of the controls are lyophilized in glass bottles and must be reconstituted before being transferred into plastic bar code-labeled vials. (Empty bar code-labeled vials are packaged in these kits with lyophilized controls.) Reconstituted controls can be stored in the plastic vials after transfer.

Controls also have color-coded caps to assist you in identification. A light brown cap is a level 1, a dark brown cap is a level 2 control.

Control bar code cards come packed in each control kit. These cards are described in more detail in the next section.



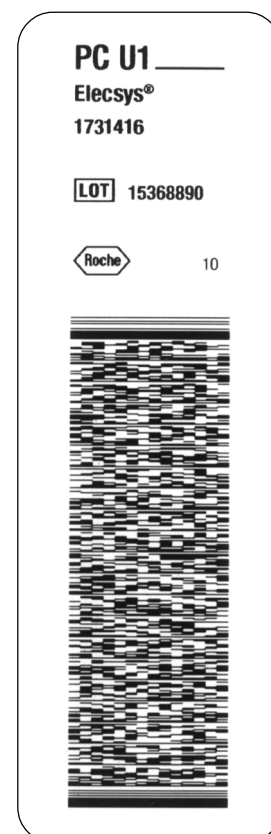
PreciControl Universal kit

Control Bar Code Cards

Each control kit comes with bar code cards. These cards are also in the PDF417 format and must be used in conjunction with the corresponding controls. Information encoded in the control bar code cards includes, but is not limited to:

- test number
- control lot number
- control code (e.g., PC U1)
- lot identifier to control bar code labels
- target or assigned values
- control ranges
- expiration date

Scan the new bar code card when a new lot of control is used.



PreciControl bar code card

Control Bar Code Labels

Each control bottle has a traditional linear bar code label that contains an identifier to link it to information encoded in the reagent bar code label and the control bar code card.

1.5 Potential Hazards and Safety Precautions

Before you start working with the analyzer, acquaint yourself with all safety precautions and regulations concerning handling of materials and the system's electrical and mechanical components.

Chemical

The operator is responsible for taking all necessary precautions against hazards associated with the use of clinical laboratory chemicals. Specific recommendations for each reagent used on the analyzer are found on the box label, package insert or product information sheet for each chemistry. Material Safety Data Sheets (MSDS) are available for Roche Diagnostics reagents.

Immediately remove any reagent spillage from the instrument.

Electrical

DO NOT attempt to open the instrument covers and work in any electronic compartment. An electrical shock may occur.

Mechanical

As with any mechanical system, there are certain precautions to take when operating the instrument. DO NOT wear loose garments or jewelry that could catch in moving mechanisms. DO NOT put your hands into the pathway of any moving parts while the analyzer is operating. Particular areas to avoid are the A-Line (rack system), B-Line (rack system), C-Line (rack system), sample/reagent probe, gripper (tip/cup carrier) and the sipper probe. Operate the instrument with the covers down unless you place additional samples on the sample disk or A-Line, or remove samples from the sample disk or C-Line. DO NOT attempt mechanical repair unless the instrument is in Stand-by or OFF.

Biohazardous Materials

As with all in vitro diagnostic equipment, patient samples and serum-based quality control (QC) products that are assayed on this system, as well as all waste from the waste containers, should be treated as potentially biohazardous. All materials and mechanical components associated with the sampling and waste systems should be handled according to your facility's biohazard procedure. Use the personal protective equipment recommended by your facility when handling any of these components.

Visual Cues

Throughout this manual, three icons are used to draw attention to certain information. These are listed below. Please familiarize yourself with the following symbols, stickers and icons.



Notes contain information about a topic in the text.



Caution

Caution messages contain information which, if not observed, could result in loss of data or in damage to the analyzer.



Warning

Warning messages contain information which, if not followed, could cause serious personal injury and/or damage to the analyzer.

Warning Stickers

There are three different stickers that appear on the 2010 analyzer. These stickers are also used to draw your attention to certain conditions. The stickers are listed below.



This sticker warns you that there are mechanisms in action within the vicinity of this sticker. In addition, these mechanisms are in contact with potential biohazards. Keep your hands out of this area while the analyzer is in operation.



This sticker warns you that there are potential biohazards within the vicinity of this sticker. Take the necessary precautions and handle all material in this area as potentially infectious.



This sticker warns you that there are corrosive or caustic reagents within the vicinity of this sticker. Take the necessary precautions and handle the reagents with care.

Potential Hazards and Safety Precautions

Mechanisms in Action



1. Verify that all analyzer covers are closed during operation.
2. Avoid touching the A-, B-, or C-Lines, sample/reagent probe mechanism, sipper probe mechanism, gripper (tip/cup carrier) mechanism, mixing mechanism and other moving parts while the instrument is operating. Otherwise, personal injury may result.
3. Verify sampling has stopped when you load additional samples on the sample disk or remove processed samples from the sample disk while the analyzer is in operation. Or, verify there is no rack movement (i.e., rack indication light is green) when you load additional sample racks on the A-Line or remove processed sample racks from the C-Line while the analyzer is in operation. Otherwise, personal injury may result.

Samples



1. Treat all samples as potential biohazards. If sample spills on the instrument, utilize correct personal protective equipment (PPE-gloves, lab coat, etc.) and wipe it off immediately.
2. Make sure that the sample does not contain any fibrin, dust, air bubbles or others insoluble contamination. If insoluble contaminants are contained in the sample, correct measuring values may not be obtained.



Waste Solution and Solid Wastes

1. Avoid direct contact with waste solution and/or solid wastes. Both should be handled as potential biohazards.
2. Dispose of waste solution and/or solid wastes according to the relevant governmental regulations.
3. Consult the reagent manufacturer for information on the concentrations of heavy metals and other toxic constituents in each reagent.
4. Do not add bleach or strong alkaline disinfectants ($\text{pH} > 9,5$) to the liquid waste container. Disinfectants combined with the contents of the liquid waste could cause potentially harmful fumes.
5. Good biodegradable of liquid waste according to DIN EN 29888.
6. With regard to AOX content (determination of adsorbable organic halogens), including liquid flow cleaning twice monthly, the liquid waste is suitable for introduction into the sewage system (DIN EN 1485).

Biohazardous parts



1. Avoid direct contact with the sample/reagent probe, sipper probe and rinse stations. Treat as potentially biohazardous areas.
2. Verify sampling has stopped before you load additional samples on the sample disk or remove processed samples from the sample disk while the analyzer is in operation. Otherwise, you may touch the potentially biohazardous sample/reagent probe.
3. Verify the tray indication light is on before loading or removing samples from the rack tray.

Reagents



1. Avoid direct contact with reagents. Direct contact may result in skin irritation or damage. Refer to the reagent kit box labels for specific instructions.
2. Avoid direct contact with CleanCell. Direct contact may result in skin irritation or damage. Refer to the CleanCell box label for specific instructions.

Additional Precautions



To Prevent Electrical Shock

1. Do not open the back cover. You may receive an electric shock.
2. Do not open the cover of the PMT high voltage supply circuit board with the power switch or circuit breaker turned on. Touching the board may cause death or severe injury.



Flammables

Avoid using dangerous flammables around the instrument. Fire or explosion may be caused by ignition.

Accuracy/Precision of Measured Results

For proper use of the instrument, measure control samples and monitor the instrument during operation.

An incorrectly measured result may lead to an error in diagnosis, therefore posing danger to the patient.

Application

The instrument is designed for clinical immunological test analysis using water-soluble samples and reagents.

Please note that other analyses may not be applicable to this instrument.

Operator Qualification

1. Operation should be conducted under the management of a technician who has undergone training at the facility specified by the sales agent.
2. For clinical tests, the instrument should be used under the management of a doctor or clinical inspector.



Operation and Maintenance

1. During operation and maintenance of the instrument, proceed according to the instructions and do not touch any parts of the instrument other than those specified.
2. Verify the front covers are closed while the instrument is in operation unless you load samples on the sample disk or A-Line or remove samples from the sample disk or C-Line.
3. Avoid touching the sample/reagent probe mechanism, sipper probe mechanism, gripper (tip/cup carrier) mechanism, mixing mechanism and other moving parts while the instrument is operating. Otherwise, the instrument may be damaged or operation may be stopped.
4. Avoid touching the sample disk or reagent disk unless the instrument is in S. Stop. Otherwise, the instrument may be damaged or operation may be stopped.
5. Do not use a cellular phone or a transceiver in the laboratory because it may interfere with the analyzer.

Installation Requirements

Installation is performed by a Roche Diagnostics representative. The customer is responsible for providing the necessary facilities as detailed in Section 2.7, Technical Data.



Restrictions on Samples and Reagent Solutions

1. The assay cups, assay tips, detection unit and liquid waste container or solid waste tray and liner are not guaranteed to be chemically resistant against organic solvents. Therefore, do not use organic solvents on these parts.
2. Avoid using sample and reagent solutions that are likely to adhere to the assay tips, assay cups, liquid waste container or detection unit.

Handling Reagent Solutions

Follow the manufacturer's instructions for use of a reagent solution.

Loading Samples and Reagents

Be sure to load samples and reagents only into the specified positions on the instrument.

If sample or reagent is spilled, this may cause a malfunction of the instrument.



Sample Disk

Verify sampling has stopped before you load additional samples on the sample disk or remove processed samples from the sample disk while the analyzer is in operation. Otherwise, the instrument may be damaged or operation may be stopped.



A-Line (rack system)

Verify that the light on the rack sampler is green, prior to adding a new rack or tray to the A-Line or removing a tray of processed samples from the C-Line while the analyzer is in operation. Otherwise, the instrument may be damaged or operation may be stopped.



Microparticle Mixer

Be careful not to bend the microparticle mixer. A bent mixer could lead to inaccurate results.



Switching On the Instrument

Never switch on the power within one second of switching it off.

Instrument Unused for a Long Time

If the instrument will not be used for a long period of time (i.e., > 7 days), contact Technical Support. Different shutdown procedures are recommended depending upon the duration of inactivity. In addition, certain procedures require the assistance of a Roche Diagnostics service representative.

Reagent Disk

Verify the reagent disk cover is locked on the reagent disk unless you are exchanging reagents.

1.6 Approvals

The Elecsys 2010 analyzer meets the requirements stated in Directive 98/79/EC of the European Parliament and the Council of the European Union (EU) on in vitro diagnostic medical devices. Furthermore, the Elecsys 2010 analyzer is manufactured and tested according to International Standard IEC 1010-1, "Safety requirements for electrical equipment for measurement, control and laboratory use, Part 1: General requirements". This International Standard is equivalent to the national standards Underwriters Laboratories (UL) 3101-1 for the USA, CSA C 22.2 No. 1010.1 for Canada, and DIN EN 61010-1 for Germany. Compliance is demonstrated by the following marks:



Complies with the IVD directive 98/79/EC.



Issued by Underwriters Laboratories, Inc. (UL) for Canada and the USA.

2. System Description

2.1 Introduction

The Roche Diagnostics Elecsys 2010 Immunoassay System is a fully automated, software-controlled system for immunoassay analysis. It is designed for both quantitative and qualitative in vitro determinations using a large variety of tests for analysis.

To assist you in quickly identifying which component is specific to either the disk or rack system, one of the following graphics appears to the right of the subsection header. If no graphic appears next to the header, then that component is common to both systems.



Disk



Rack

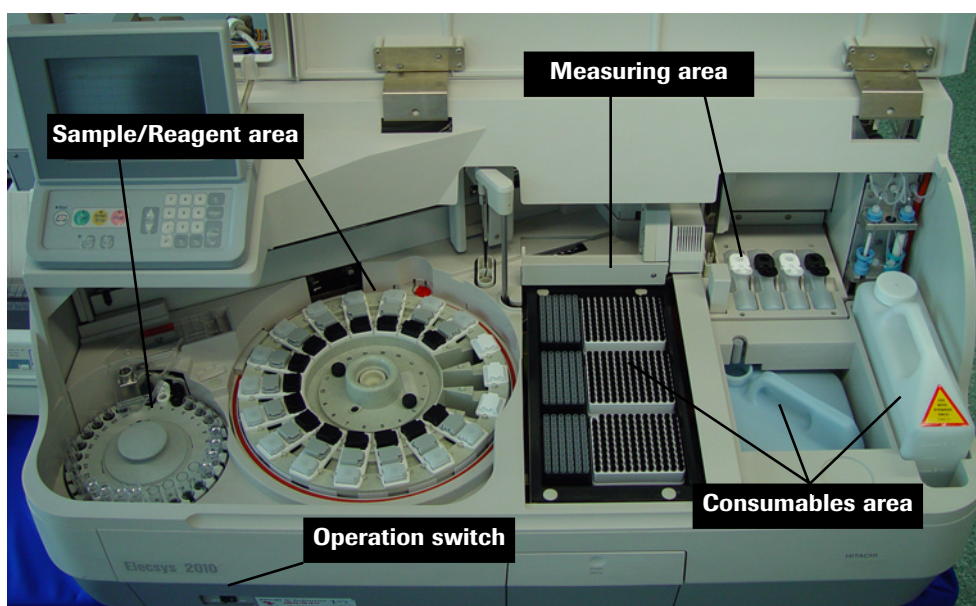
The Control Unit

The control unit, consisting of a touchscreen and a keyboard, is located on the left of the analyzer. Also included as part of the control unit is the floppy disk drive, located inside the door above the solid waste tray.



Control unit

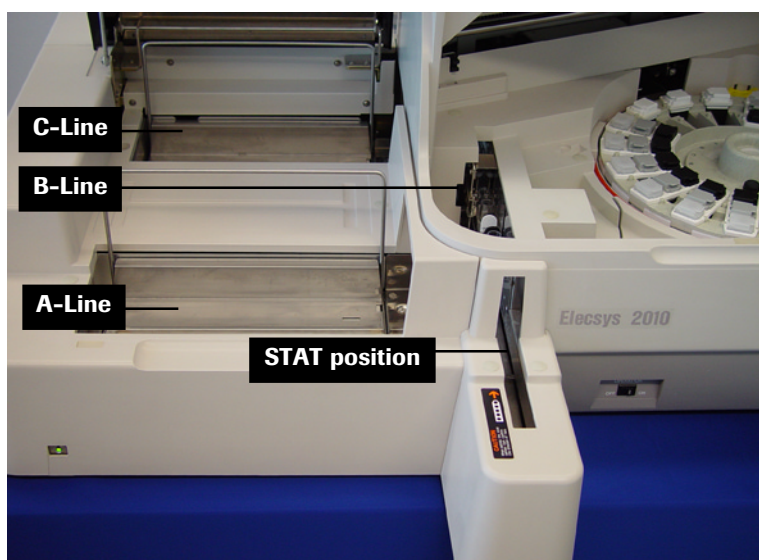
The Analyzer Unit



The analyzer unit on the disk system consists of the:

- sample/reagent area
- consumables area
- measuring area
- operation switch

The only difference on the rack system is in the sample area. The sample disk is replaced by a rack sampling unit. Refer to the photo below.



Sample/Reagent Area

The sample/reagent area comprises the left half of the analyzer and consists of a sample disk or rack sampler (rack system), rack bar code reader (rack system), sample/reagent (S/R) probe, bar code reader, bar code card reading station, reagent disk, a cap open/close mechanism, a microparticle mixer, probe/mixer rinse station and sample/reagent (S/R) pipettor.

The sample disk accommodates up to 30 samples. The A-Line of the rack sampler accommodates 75 samples on a single tray (15 racks at a time; each rack with five positions) and 25 samples in the input buffer for a total capacity of 100 samples. The reagent disk, temperature controlled at 20 ± 3 °C, accommodates up to 18 reagent packs.

Consumables Area

The consumables area is on the right of the analyzer, consisting of three tip trays, three assay cup trays, a gripper unit, cup disposal opening, liquid waste container, solid waste tray and liner and system water container.

Measuring Area

The measuring area includes the incubator, the sipper probe, sipper rinse station, system reagents

(ProCell and CleanCell), an aspiration station, sipper pipettor and the detection unit. The sipper probe aspirates the incubated reaction mixture into the detection unit for result determination.

Operation Switch

The operation ON/OFF switch is located on the front left of the analyzer. In addition, there is a circuit breaker for the analyzer located on the right side panel and a rack sampler circuit breaker located on the left side of the rack sampler.

2.2 Control Unit Components

The control unit consists of a color touchscreen monitor, a keyboard, floppy disk drive unit and an external printer.

Touchscreen

The touchscreen monitor is located on the left of the analyzer and displays the software. The Elecsys 2010 software displays menu items as folders. Each folder is accessed by touching the corresponding folder tab.



Touchscreen

Keyboard



Keyboard

The 2010 keyboard consists of global action keys, navigation keys and numeric keys. These keys are described in detail in the Software Guide.

Floppy Disk Drive

The floppy disk drive is located behind the front access door above the solid waste tray. The drive holds a data disk required for analyzer operation.



Floppy disk drive

Data Disk

The data disk contains a number of files necessary for the analyzer and the software to work together. These files include:

- assay reference tables: these tables contain information that is linked to data encoded in the reagent bar code (e.g., test number, test code, available units and unit conversion factors)
- calibration data
- result messages
- total number of determinations per reagent pack (i.e., 100 or 200)
- orders and test results (up to 600 can be stored)
- all instrument adjustments
- serial number of analyzer (entered by Service during software installation)



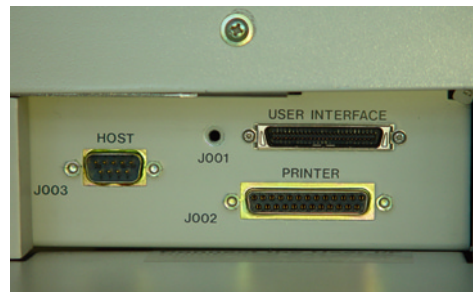
Caution

It is important to keep each data disk with its analyzer. Using a data disk containing adjustments from a different analyzer results in mechanical movement errors. Use of an incorrect data disk causes alarm 57-01-01: Serial no. check error to occur.

External Printer

The instrument uses an 80-column, graphics-capable, dot matrix printer.

The printer is connected to the analyzer via a parallel printer port. The port is located on the left side of the analyzer directly below the touchscreen cable port. Examples of each printed report are found in Chapter 8 of the Software Guide.



Location of the printer port

Host Interface

The instrument can be bidirectionally interfaced with a host computer. Details concerning the interfacing of the 2010 analyzer are available by contacting Technical Support.

2.3 Sample/Reagent Area Components

The sample/reagent area consists of a sample disk or rack sampler (rack system), rack ID bar code reader (rack system), sample/reagent (S/R) probe, bar code reader, bar code card reading station, reagent disk, cap open/close mechanism, microparticle mixer, probe/mixer rinse station and sample/reagent (S/R) pipettor.



Sample Disk

The sample disk has 30 positions for samples, calibrators and controls. Patient samples may be placed in either primary sample tubes or sample cups. Built-in adapters allow intermixing of different size primary sample tubes.

Sample tubes that may be used are listed in chapter 2.7 Technical Data.

Sample cups [2 mL (Standard) Hitachi cups only] may be placed directly on the sample disk or on top of 16 mm primary sample tubes.



Caution

Micro cups cannot be used on the 2010 analyzer!



Sample disk



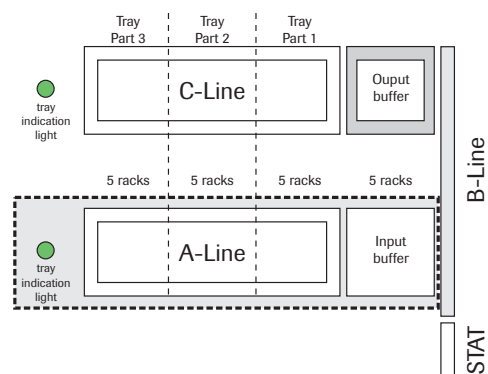
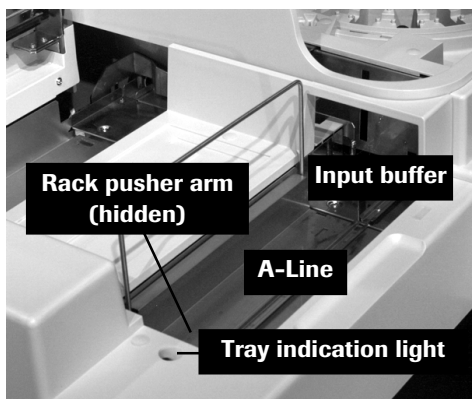
Rack Sampler

The rack sampler consists of an A-Line, B-Line, C-Line and STAT position.

A-Line

Specimens are placed in 5-position sample racks and are loaded onto a tray. Once a tray is loaded, additional racks can be added to the tray one at a time during operation, provided the tray indication light is green (ON). If the light is out (OFF), the pusher arm is preparing to move. The pusher arm is located at the far left of the A-Line and pushes the sample racks forward and onto the B-Line.

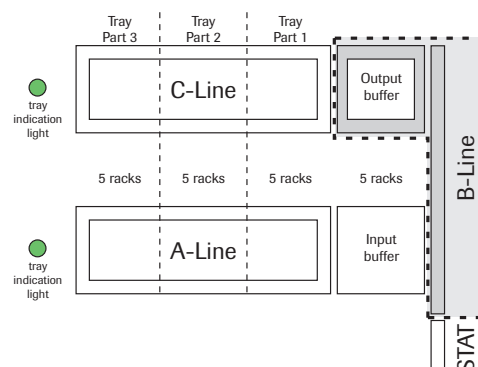
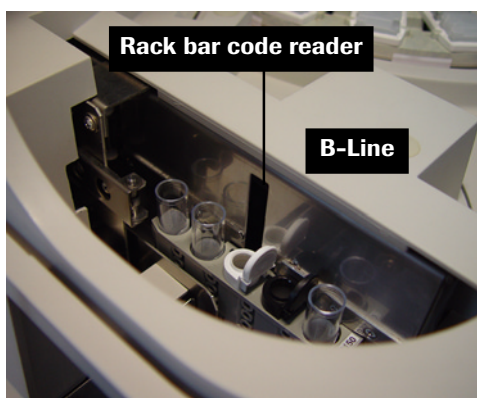
The A-Line holds a tray that accommodates 15 racks at one time. Another five racks can be in the input buffer. Therefore, you can have a total of 100 specimens loaded at any one time. Refer to the photo and graphic below.



A-Line of the rack sampler

B-Line

The B-Line transports the sample racks, single file, first to the rack bar code reader. Here each position in the rack is scanned for a sample bar code. After the last position is scanned, the bar code reader scans the rack ID. After the last specimen is sampled, the rack is transferred via the output buffer onto the tray on the C-Line. Refer to the photo and graphic below.

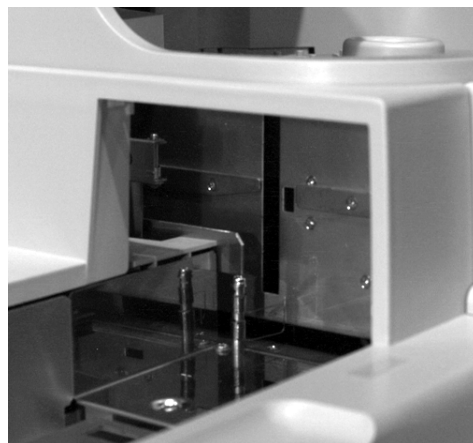


B-Line of the rack sampler

Rack Bar Code Reader

The rack bar code reader reads both sample bar code labels and the rack bar code label. The bar code reader is auto-discriminating, allowing the use of various types of bar codes during operation. Bar code symbologies read include:

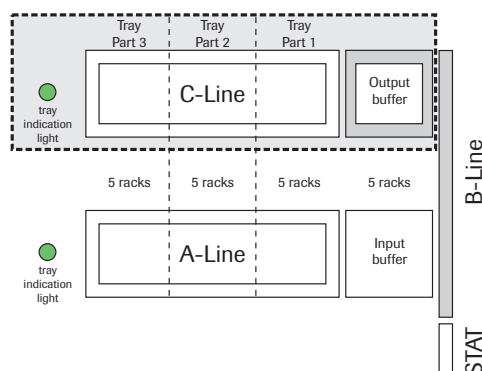
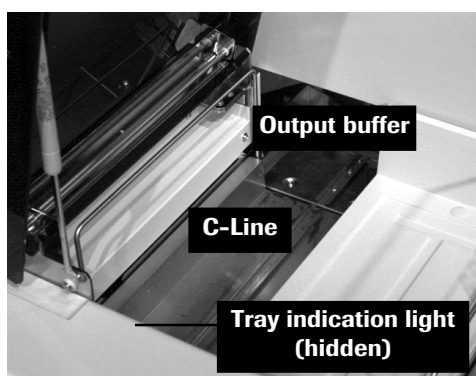
- NW7 (Codabar)
- Code 39
- Code 128
- Interleaved 2 of 5



Rack bar code reader

C-Line

Racks are off-loaded from the B-Line into the output buffer. If there is no tray, up to 5 racks can enter the output buffer, thereafter the sampling procedure is stopped. When the sixth rack is moved into the output buffer, a rack is pushed onto the tray on the C-Line. You can remove the tray from the C-Line any time the tray indication light is green (ON). If the light is out (OFF), the system is preparing to push a rack onto the C-Line tray. You cannot remove single racks from the C-Line. You must remove an entire tray at one time.



C-Line of the rack sampler

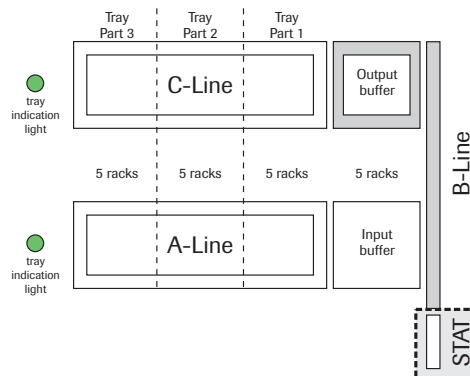
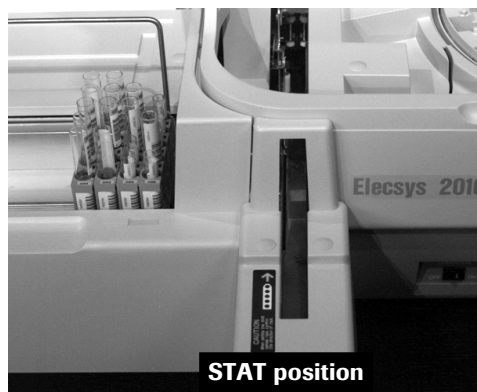
If the tray is removed, the system continues to push racks into the output buffer. If the buffer fills and there is no tray, the analyzer issues an alarm and stops sampling racks.



Output buffer with racks

STAT Position

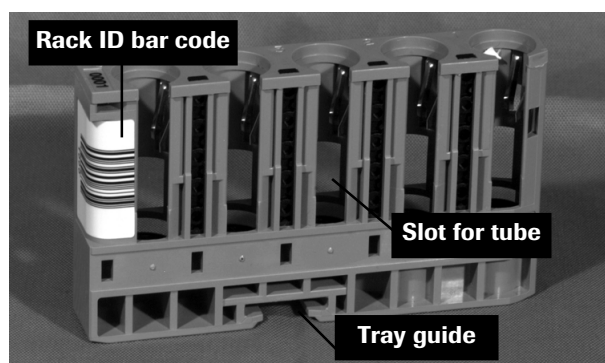
The STAT position is located at the front of the analyzer and is in line to feed directly onto the B-Line. Place a rack in the position as directed on the label and press the **STAT** key. When the rack currently being sampled is completed, the STAT rack is pushed onto the B-Line and is sent on to the rack bar code reader and sampling position.



STAT position of the rack sampler

Sample Rack

Sample cups, primary sample tubes, calibrator or control vials are placed in sample racks shown below. Each sample rack holds a maximum of five samples. Each tube slot contains adapters that allow the rack to hold different sizes of primary sample tubes. Each rack has a unique ID found on the bar code label on the back end of the rack. This rack ID is read by the bar code reader and transferred to the system. This ID appears on the screens in the software and on the reports.

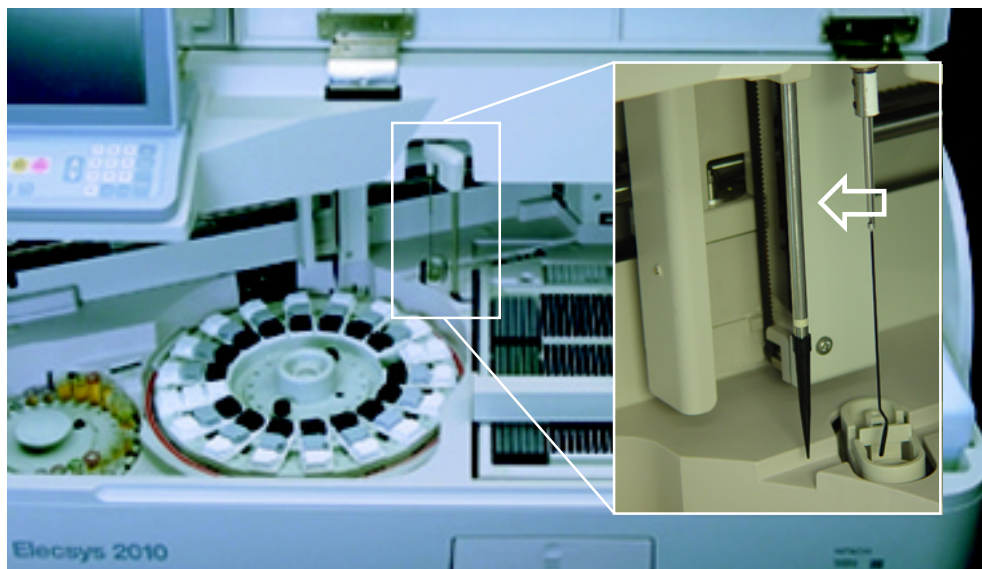


Sample rack

Sample/Reagent (S/R) Probe

The sample/reagent probe is located on the back left wall of the analyzer and is mounted on an arm (S/R arm) that moves horizontally between the sample and reagent disk. The probe uses disposable tips to avoid sample carryover, and has liquid level and clot detection for accurate pipetting. Liquid level detection is accomplished by capacitance measurement. Clot detection is accomplished by a pressure transducer.

A new assay tip is utilized with every new pipetting sequence. For example, TSH = 1 tip for R1, R2 and sample, then one new tip for microparticles. The tip is washed externally at the rinse station between each aspiration. Additional tips are used for sample dilutions or pretreatment.



S/R probe with tip



Ensure that there is no foam on the surface of the sample.

Bar Code Reader

During a sample scan, the bar code reader scans the information on the bar code-labeled primary sample tubes, calibrators or controls, and transmits it to the software. During a reagent scan, the reader rotates to the reagent disk side to read the 2-dimensional bar code labels on the reagent packs.

The bar code reader is located toward the back wall of the analyzer.



On the disk system:

- it can be seen when either the sample disk or reagent disk is removed.
- to read bar code labels, the bar code reader rotates between the sample and reagent disks, and the card reading station.



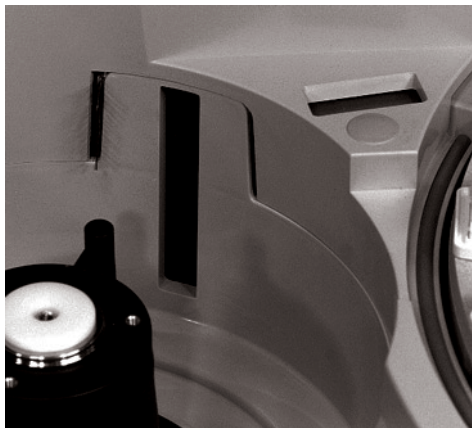
On the rack system:

- it can only be seen when the reagent disk is removed.
- to read bar code labels, the bar code reader rotates between the reagent disk and the card reading station.
- A second bar code reader scans sample bar codes and rack ID bar codes.

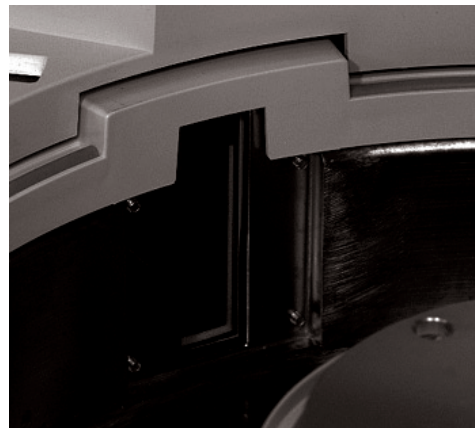
The bar code reader is auto-discriminating, allowing the use of various types of bar codes during operation. In addition, this bar code reader also reads PDF417.



PDF417 can only be used for reagent bar codes and bar code cards.



Bar code reader (sample disk side)



Bar code reader (reagent disk side)

Bar Code Card Reading Station

At this station, the bar code reader scans calibrator and control information from the calibrator or control bar code card. These cards are packed in calibrator or control kits.



On the disk system:

- it is located between the sample disk and reagent disk.



On the rack system:

- it is located to the back left of the reagent disk.



Bar code card reading station

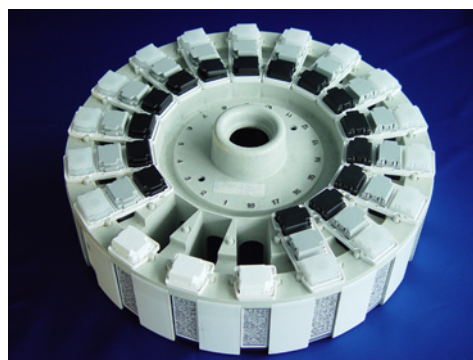
Reagent Disk

The reagent disk contains 18 positions for assays, diluent or pretreatment reagent. These 18 positions can be used in any combination, with the following restrictions: max. 15 assays, max. 8 diluents, max. 9 pretreatments.

The reagent disk is temperature controlled at 20 ± 3 °C.



Diluent or pretreatment reagent can be placed in ANY position on the reagent disk. More than one reagent pack can be loaded on the reagent disk for each test.



Reagent disk

Reagent Cap Open/Close Mechanism

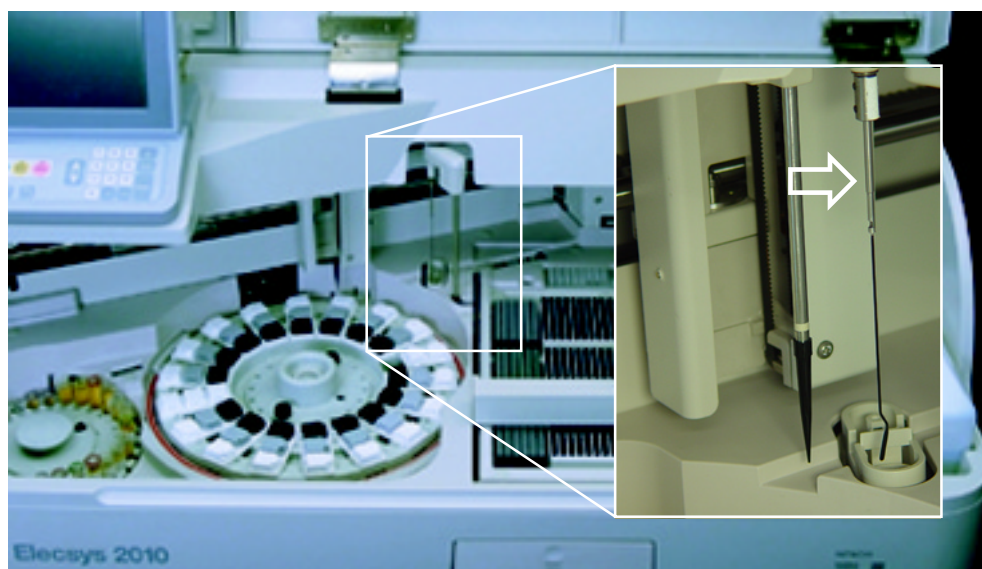
To prevent reagents from evaporating, and to promote ease of use for the operator, the reagent disk utilizes a reagent cap open/close mechanism during reagent pipetting. The mechanism is located on the back wall of the reagent disk compartment and emerges when reagents need to be opened or closed. Caps are opened prior to pipetting or mixing the specific reagent (e.g., M, R1 or R2) and are closed when pipetting or mixing for the specific reagent (e.g., M, R1 or R2) is completed.



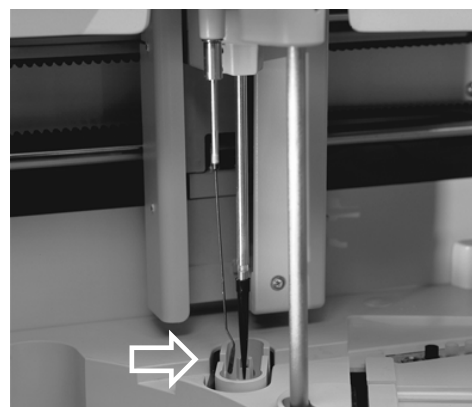
Reagent cap open/close mechanism

Microparticle Mixer

The mixer is utilized to mix the microparticles to ensure a homogeneous suspension before aspiration. The mixer is located to the right of the reagent disk. In its home position, it occupies the space directly to the left of the S/R probe.

**Microparticle mixer****Probe/Mixer Rinse Station**

The rinse station rinses the assay tip or mixer externally with system water between aspirations, or before and after microparticle mixing. The rinse station is located below the S/R probe and mixer when the probe is in its Stand-by position and the mixer is in its home position.

**Rinse station**

Sample/Reagent (S/R) Pipettor

The S/R pipettor is located on the back right of the analyzer. The pipettor is filled with system water and uses positive displacement to aspirate and dispense from the S/R probe.

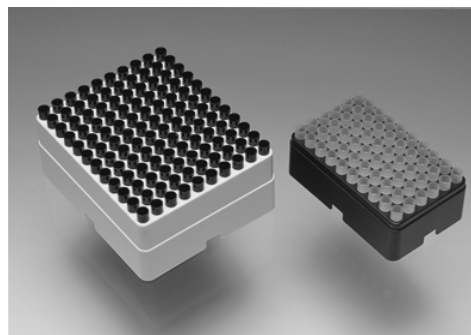


Sample/reagent pipettor

2.4 Consumables Area Components

The consumables area consists of three assay cup trays, three tip trays, gripper, incubator, cup disposal opening, pipetting station, liquid waste container, system water container and solid waste tray and liner.

One tip tray holds up to 120 tips, and one cup tray holds up to 60 cups. Therefore, a total of 360 tips and 180 cups can be placed on the analyzer.



Tip tray and cup tray

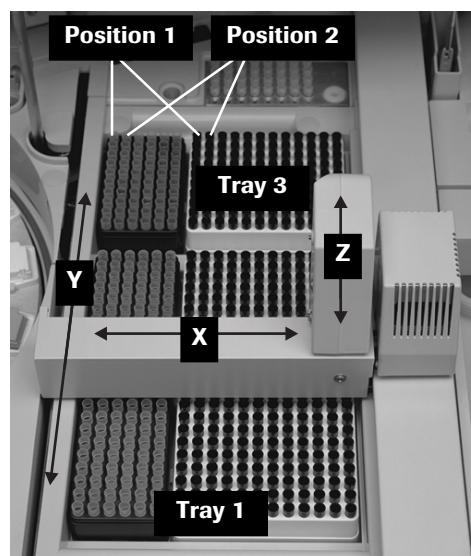
Gripper

The gripper can move in three directions:

- X (left and right)
- Y (forward and back)
- Z (up and down)

It is also equipped with gripping fingers for gripping a tip or assay cup. The gripping fingers grip a tip from the tip tray, or a cup from the cup tray and deliver it to the pipetting station. Then, at the appropriate time, the gripper moves the assay cup to the incubator, then to the aspiration station, and finally to the cup disposal opening.

During operation, the analyzer starts utilizing tips and cups from tray 1, position 1. As soon as tray 1 is empty, the analyzer starts using tray 2. As soon as tray 2 is empty, the analyzer continues with tray 3. When tray 3 is empty, the analyzer returns to tray 1, if a new tray has been reloaded.



Gripper and trays

Cup Disposal Opening

Assay cups are discarded through a cup opening located directly to the left of the incubator.



Cup disposal opening

Pipetting Station

A five position pipetting station is located to the upper left of the incubator. Assay cups and tips are moved by the gripper to this location for sample and reagent pipetting, sample dilution and sample pretreatment. The assay tips are discarded at the tip eject station at the far right of the station. Positions 1 and 2 are used for tips and positions 3 and 4 are used to hold cups for dilution or pretreatment. Position 5 is the position where the S/R probe pipettes sample and reagent.



Pipetting station

System Water Container

The system water container is located in front of the pipettors and to the right of the liquid waste container. It holds three liters of system water. An alarm is issued when the system water container is empty. A float mechanism sensor located beneath the aspiration inlet, triggers the alarm on the **INVENTORY** screen.



Removing the system water container during operation causes the analyzer to enter P. Stop status.



System water container

Liquid Waste Container

The liquid waste container is located in front of the ProCell and CleanCell reagents. It holds four liters of waste and issues an alarm when approximately three-quarters full. The alarm is triggered by a weight-sensitive mechanism that activates a photosensor located in the compartment holding the container. An alarm is also issued when the container is improperly positioned. This alarm is triggered by a plate mechanism that activates a photosensor located at the front of the compartment.



Removing the liquid waste container during operation or an improperly positioned container causes the analyzer to enter E. Stop status.



Liquid waste container

Solid Waste Tray and Liner

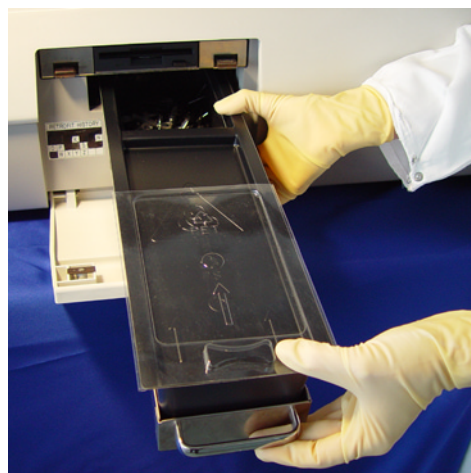
The solid waste tray and liner is located behind the front access door on the analyzer. Used assay cups and tips are discarded into the waste tray during operation.

A disposable liner (Clean-Liner) made of polystyrene is placed inside the solid waste tray. The Clean-Liner has a sliding cover to reduce potential splashing and to prevent tips and cups from falling out of the tray upon removal from the analyzer. During operation, the sliding cover must be open. The tray shakes periodically during operation so that used tips and cups do not accumulate at one end of the tray.

An alarm is issued when either the tray is full (max. 1100 tips and cups) or if the tray and liner are missing. The presence of a tray is monitored by a photosensor.



Removing the solid waste tray during operation causes the analyzer to enter E. Stop status.



Solid waste tray and liner

2.5 Measuring Area Components

The measuring area includes the incubator, aspiration station, sipper probe, sipper rinse station, sipper pipettor, system reagents (ProCell and CleanCell) and the detection unit.

Incubator

The incubator is maintained at a specific temperature ($37.0^{\circ}\text{C} \pm 0.3^{\circ}\text{C}$) for the reaction of the sample and the reagents that have been dispensed into a cup. The incubator is equipped with 32 positions.

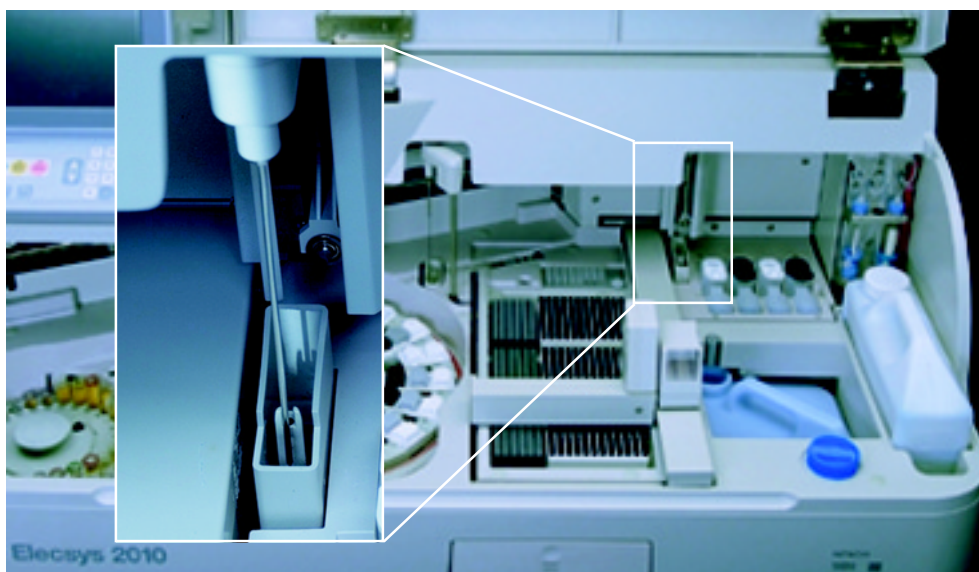
When an assay is ready for measurement, the assay cup is transferred by the gripper to the aspiration station, and the sipper probe aspirates the reaction mixture for measurement. The aspiration station, located in the lower right corner of the incubator, is not temperature controlled.



Incubator

Sipper Probe

The sipper probe aspirates the reaction mixture into the measuring cell. ProCell and CleanCell are also aspirated by the sipper probe. The sipper probe is located to the right of the incubator. The sipper rinse station externally washes the sipper probe with system water between measurements. When the sipper probe is in its Stand-by position, the probe is located directly above the rinse station.



Sipper probe and rinse station

Sipper Pipettor

The sipper pipettor is located directly to the right of the sample/reagent pipettor. It uses positive displacement of water to aspirate and dispense from the sipper probe.



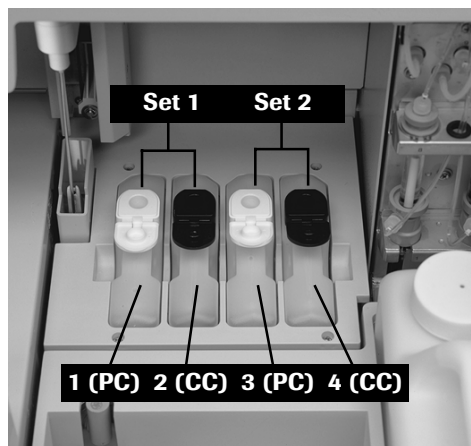
Sipper pipettor

System Reagents (ProCell and CleanCell)

ProCell and CleanCell are located behind the liquid waste container. ProCell is the buffer solution containing tripropylamine (TPA). These bottles are identified with white caps.

CleanCell is the cleaning solution used to clean the measuring cell after measurement. CleanCell bottles are identified with black caps.

The reagent compartment is keyed to ensure the correct reagent is placed in the proper position. Two bottles of each reagent are stored on the analyzer, temperature controlled at $28.0\text{ }^{\circ}\text{C} \pm 2.0\text{ }^{\circ}\text{C}$.



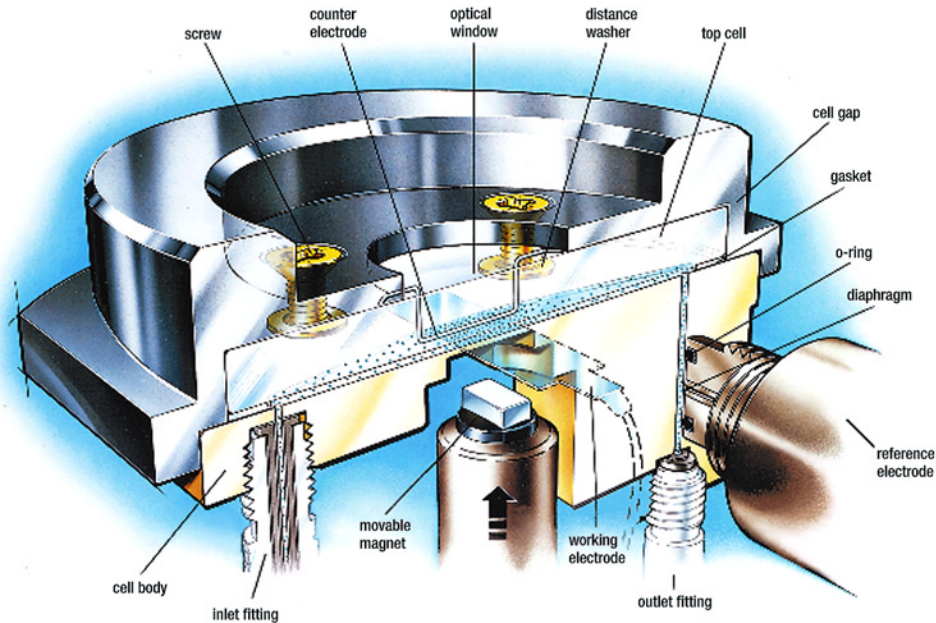
ProCell (PC) and CleanCell (CC)

When starting from Stand-by, the sipper probe always attempts to first use ProCell and CleanCell from bottle set 2. If the quantity is insufficient, bottle set 1 is used. When starting from S. Stop or R. Stop, the bottle set in use when the analyzer was previously in Operation is pipetted.

The analyzer can operate with one bottle set of ProCell and CleanCell reagent, but they must be placed in positions 1 & 2 or 3 & 4. Refer to the photograph above.

Detection Unit

The detection unit is the core of the Elecsys 2010 system. The detection unit contains the photomultiplier tube, peltier, flow-through measuring cell, magnet drive assembly and an amplifier circuit board. The temperature is maintained at $28.0\text{ }^{\circ}\text{C} \pm 0.5\text{ }^{\circ}\text{C}$.



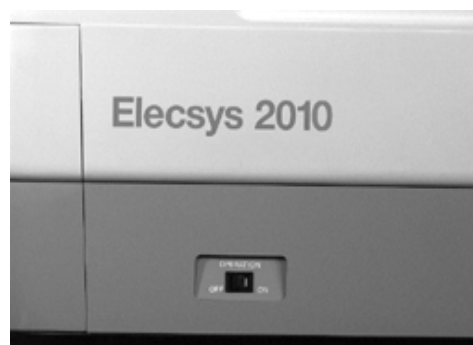
Measuring cell of the detection unit

2.6 Power Components

Operation Switch

The operation switch is located on the lower left front side of the analyzer. Use this switch to turn OFF the analyzer to perform certain maintenance procedures or when the system is not in use for extended periods of time (e.g., overnight). The operation switch also turns OFF the power to the touchscreen.

Provided the circuit breaker is ON, the reagent disk and system reagent compartment temperatures are maintained while the operation switch is OFF.



Operation switch

Circuit Breaker

The circuit breaker is located on the right side panel of the analyzer above the power supply cord. The circuit breaker controls the power supplied to the temperature controlled reagent compartments when the operation switch is OFF. The circuit breaker must be in the **I** (ON) position whenever reagents are stored on the analyzer and to maintain liquid in the measuring cell.

When connecting or disconnecting the host cable, power the analyzer off at the circuit breaker only



To disconnect the analyzer from the supply source, the circuit breaker must be in the **O** (OFF) position and the power cord must be removed.



Circuit breaker

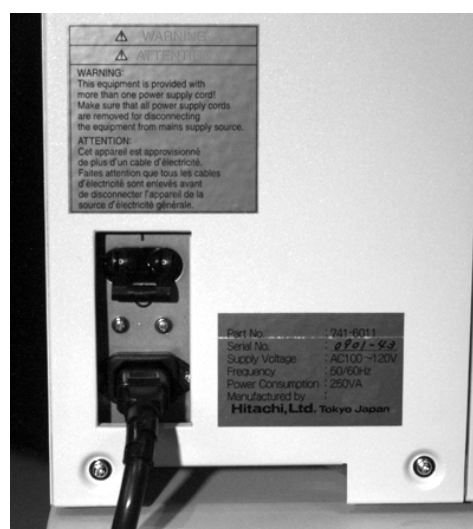


Rack Circuit Breaker

There is a circuit breaker located on the left side of the rack sampler. This controls power to the sampler unit. The circuit breaker should be kept in the **I** (ON) position at all times. Use the operation switch to power ON and OFF the rack system.

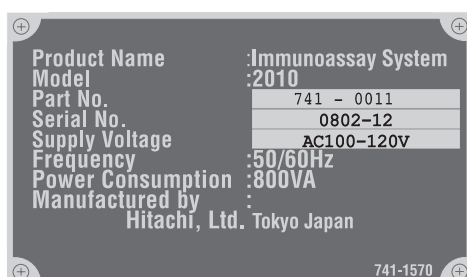


To disconnect the analyzer from the supply source, the circuit breaker must be in the **O** (OFF) position and the power cord must be removed.

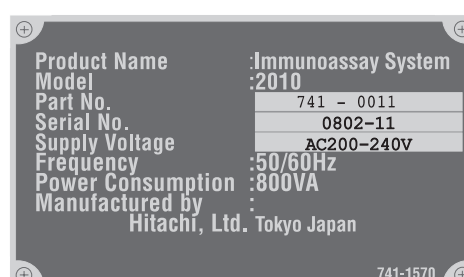


Rack circuit breaker

2.7 Technical Data





Analyzer plate (US)



Analyzer plate (Europe)

Instrument Dimensions

Analyzer	Height	Depth	Width	Weight
	22.05 in	28.7 in	47.2 in	~ 375 lbs
	56 cm	73 cm	120 cm	170 kg
	[not including the touchscreen]			
	22.05 in	37.5 in	67.2 in	~ 462 lbs
	56 cm	95 cm	170 cm	210 kg
	[not including the touchscreen]			

Electrical

Installation requirements	Pollution degree: 2 (IEC 1010-1) Overvoltage category: II (IEC 664) The Elecsys 2010 analyzer must be connected to a three-wire power supply cord with a safety ground.
Supply voltage/frequency	100-120 VAC 50/60 Hz single phase or 200-240 VAC 50/60 Hz single phase The range of supply voltage and frequency should only be configured to laboratory specifications by Roche Diagnostics service personnel.
Power consumption	800 VA
Heat generation	approx. 2,879 kJ/hr resp. 688 kcal/hr resp. 2,730 Btu/hr

System Description

Environmental Conditions

Temperature	18 °C to 32 °C 64.4 °F to 89.6 °F
Temperature variation	Max. \pm 2 °C/hour Max. \pm 3.6 °F/hour
Humidity	20% to 80%

Noise Level (DIN 43635)

Stand-by level	60 dBA
Operation level (average)	63 dBA
Operation level (maximum)	70 dBA

Water Supply

Water container	3 Liters
Water requirements	< 10 μ S/cm or > 0.1 megohm, bacteria-free
Water consumption	approx. 3 L for 250 tests approx. 12 mL/cycle


Liquid Waste

Liquid waste container	4 Liters
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Throughput Rate

Assay measurements	approx. 86 tests/hour
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Sampling System

Sample/Reagent pipettor principle	conductive disposable tip handling
Sample/Reagent pipettor precision	< 1.5% CV at 10 μ L < 1% CV at 50 μ L
Sample volume per test	10 μ L to 50 μ L
Sample detection	Liquid level detection and clot detection
Sample loading capacity	

30 positions for samples, controls and calibrators



tray – 15 racks with 5 positions each for samples, controls and calibrators = 75

tray with input buffer – 20 racks with 5 positions each = 100

STAT capacity



any unoccupied position on the sample disk



STAT position at the front of the analyzer

Bar code symbologies	PDF417 NW7 (Codabar) Code 39 Code 128 Interleaved 2 of 5
Assay tips	360 tips (3 trays; 120 tips/tray)
Assay cups	180 cups (3 trays; 60 cups/tray)
Sample cups	2 mL (Standard) Hitachi cup; NO micro cups
Primary sample tubes	13 x 75 mm 15.65 x 100 mm
(external diameter x height)	13 x 100 mm 16 x 75 mm
	13.25 x 78 mm 16 x 100 mm
	14 x 100 mm 16.2 x 100 mm
	15.3 x 75 mm 16.5 x 92 mm



Sample container dead volume

Sample Container	Tube height	"Normal" dead volume	"Reduced" dead volume
standard Hitachi cup directly on the sample disk	—	200 µL	100 µL
standard Hitachi cup on top of a primary sample tube (ø = 16 mm)	75 mm	200 µL	150 µL
standard Hitachi cup on top of a primary sample tube (ø = 16 mm)	100 mm	200 µL	150 µL
primary sample tube (ø = 13 mm)	75 mm	600 µL	—
primary sample tube (ø = 13 mm)	100 mm	600 µL	—
primary sample tube (ø = 16 mm)	75 mm	1000 µL	—
primary sample tube (ø = 16 mm)	100 mm	1000 µL	—
calibrator/control vial	—	150 µL	150 µL



Caution

A reduced dead volume may only be used with Hitachi standard cups (not with primary or secondary cups).



Sample container dead volume

Sample Container	Tube height	"Normal" dead volume	"Reduced" dead volume
standard Hitachi cup directly on the sample rack	—	200 µL	100 µL
standard Hitachi cup on top of a primary sample tube (ø = 16 mm)	75 mm	200 µL	100 µL
standard Hitachi cup on top of a primary sample tube (ø = 16 mm)	100 mm	150 µL	100 µL
primary sample tube (ø = 13 mm)	75 mm	600 µL	—
primary sample tube (ø = 13 mm)	100 mm	600 µL	—
primary sample tube (ø = 16 mm)	75 mm	1000 µL	—
primary sample tube (ø = 16 mm)	100 mm	1000 µL	—
calibrator/control vial	—	150 µL	150 µL

Reagent System

Reagent disk temperature	20 °C ± 3 °C (68 °F ± 5.4 °F)
Reagent capacity	15 assays in 18 reagent positions
R1/R2 consumption	50 to 80 µL per reagent dependent upon the assay
Microparticle consumption	30 to 50 µL dependent upon the assay
Reagent detection	liquid level detection
Positive reagent identification	2-dimensional bar code (PDF417)
Automatic dilution	available up to 1:100
Evaporation protection	reagents are automatically opened and closed
Inventory control	automatic based on counting (reagent disk) or liquid level detection (ProCell/CleanCell)

Incubation System

Incubator capacity	32 assay cups
Volume of assay cups	200 µL
Incubation temperature	37.0 °C ± 0.3 °C (98.6 °F ± 0.5 °F)

Measuring System

Measuring method	integral measuring of an electrochemiluminescence signal
Calibration mode	2-point calibration
Test protocols	28 test methods
ProCell consumption	approx. 2 mL per cycle
CleanCell consumption	approx. 2 mL per cycle
Cycle time	42 sec.

Control System

Floppy disk	3 1/2 inch / 1.44 MB
Host interface	CCITT V. 24/RS-232-C (bidirectional) The host computer should comply with the requirements of IEC (950).
External printer	parallel (Centronics)
Optional module	Laboratory System Manager (LSM)
Touchscreen monitor	VGA - LCD with 640 x 480 pixel

3. Mechanical Theory

3.1 Introduction

The Elecsys 2010 analyzer automates the immunoassay reactions utilizing electrochemiluminescence (ECL). These reaction methods are described in detail in Chapter 4, ECL Technology. The individual test steps and how the system performs the necessary procedures are discussed here.

Test Protocols

There are 28 test protocols or test steps that can be used on the analyzer. These protocols are predefined by Roche Diagnostics for each test and cannot be changed by the operator.

General Assay Sequence

An immunological ECL test is made up of various pipetting steps, at least one incubation period and a measurement step. Generally at least three test components (sample, reagent and microparticles) are pipetted into an assay cup. After the appropriate incubation period, the reaction mixture is aspirated into the measuring cell where the measurement process takes place. Each of the required pipetting cycles is performed within a defined period (42 seconds).

The number of pipetting steps, as well as the make up of the reaction mixture are dependent on the test method (1 or 2 step test). For some methods, predilution with diluent and/or pretreatment with a special reagent is necessary. Thus the number of pipetting steps is increased.

After each pipetting step the sample/reagent (S/R) probe tip is cleaned and, if necessary, the microparticle mixer and sipper probe are also cleaned.

The following steps apply in principle to all methods. The sequence of the individual processes differ from test to test.

Preparative Operations

Once the analyzer's power is switched ON, the initialization process is started. During initialization, the mechanisms are reset to their home positions.

Run Operation

After the appropriate test selections are made in the software for patient samples, operation is started according to the predetermined test protocol for each assay selected. Initially, at least one reagent (R1 or R2) and the sample or microparticles (M) are aspirated one after another by the S/R probe. After each aspiration, the outside of the S/R probe tip is cleaned at the rinse station. The sample and reagents are dispensed into a new assay cup and the assay tip is ejected into the solid waste tray.

For some tests that require sample dilution or pretreatment, diluent or pretreatment reagent is pipetted together with sample into an assay cup. An aliquot of the diluted/pretreated sample is then dispensed with reagent into a second assay cup. Therefore, certain tests with predilution/pretreatment may require two or more assay cups. For additional information refer to Section 3.3, Dilution Steps.

First Incubation at 37 °C

The incubation times are 4.5 or 9 minutes long, depending on the test. Some tests require only two incubation periods, whereas tests with pretreatment tests can require three incubation periods. During the incubation step(s) the immune complex products are formed.

Additional Reagent Pipetting

Some assays (usually those with multiple incubation steps) require additional reagent pipetting. As in the initial reagent pipetting step, a new pipette tip is picked up prior to reagent aspiration. The S/R probe tip is washed at the rinse station after each liquid aspiration. The liquid is then dispensed into the corresponding assay cup where the sample and other liquids were dispensed in the first pipetting step. The probe rises while dispensing the reaction mixture back into the cup, thereby mixing the solution and accelerating the reaction in the cup. The pipette tip is ejected into the solid waste tray when pipetting is complete.

Second Incubation at 37 °C

If necessary, a second incubation step (4.5 or 9 minutes) occurs.

If using a pretreatment assay, the second incubation is similar to that described above for "First Incubation at 37 °C".

Additional Reagent Pipetting (Pretreatment assays)

For pretreatment assays, reagent pipetting similar to that described above for "Additional Reagent Pipetting" occurs.

Third Incubation at 37 °C (Pretreatment assays)

If necessary, a third incubation step (9 minutes) occurs for pretreatment assays.

Reaction Mixture Aspiration and Measurement

In this process the sipper probe first aspirates ProCell (tripropylamine solution, TPA) to prepare the measuring cell. Then, the sipper probe aspirates the reaction mixture from the assay cup and transfers it to the measuring cell. The sipper probe is washed at the rinse station and ProCell is aspirated again to rinse away the unbound reagent and sample constituents. Next, the ECL reaction in the measuring cell occurs.

Measuring Cell Cleaning

Once the measurement is complete, the measuring cell is cleaned with CleanCell and prepared for a new measurement process.

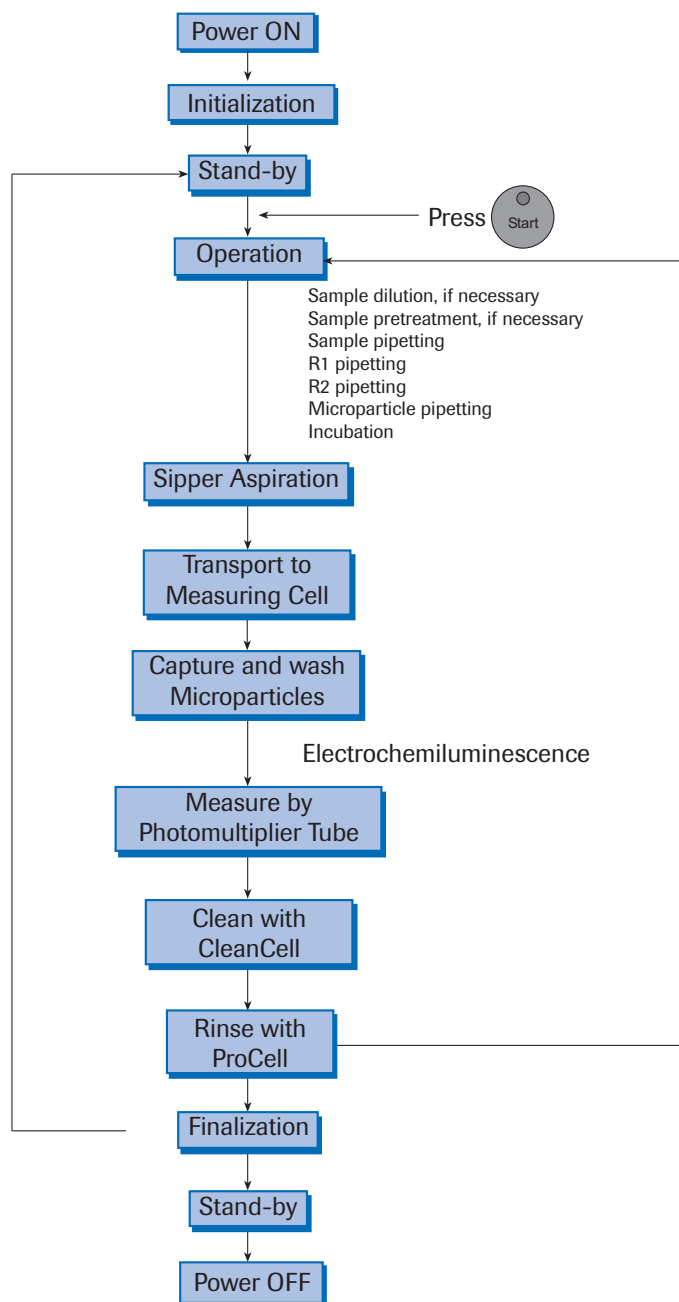
It takes 42 seconds (one pipetting cycle) from the aspiration of the reaction mixture by the sipper probe until the measuring cell is filled with ProCell and ready for the next sample.

Finalization

30 Minutes after documentation of the last result, the sipper pipettor flushes system water through the sipper probe, and then fills the measuring cell with ProCell before the analyzer returns to Stand-by. After this procedure periodically all 30 minutes the waste pump of the S/R rinse station is running for 2 seconds (waste consumption approx. 12 mL). This procedure will be stopped after switch off the operation switch.

Operation Flow in Analysis

An operational flow chart is shown below.



Operational flow chart

3.2 Detailed Assay Sequence

The mechanical process of the instrument is described below using a sandwich test, TSH, as an example. This example assumes that the reagent pack was already registered by the analyzer and does not need calibration. All results are calculated based on an existing lot calibration.

Preoperation Steps

When **START** is pressed from Stand-by, the following preoperative steps occur.

- A. The analyzer resets all mechanisms to their respective home positions and accesses the data disk. Next, the S/R pipettor primes the S/R probe.
- B. The gripper checks for a tip in position number 1 of the tip trays. If this position is empty, the gripper remembers where it last left off and checks that position. If this position is empty, the gripper considers the whole tray empty and the **INVENTORY** screen is updated accordingly.



If the analyzer is in S. Stop, the gripper remembers where it last left off and checks for a tip in that position.

1. During the tip check, the S/R probe is checked for the presence of a tip. The probe moves to the tip eject station and performs the movements to eject a tip. If a tip is present it is ejected.
2. After the tip check is complete, the assay cups are checked in the same manner. During the cup check, the analyzer finishes priming the probes.
3. Next, the gripper checks the last three of the five positions on the pipetting station.
If a cup is present, the analyzer goes through the steps of a cup disposal. The gripper places a tip in position 1 of the pipetting station. Then, the S/R probe picks up the tip in position 1 of the pipetting station. The S/R probe descends into the assay cup and attempts to aspirate any possible liquid from the cup. The gripper picks up the cup and discards it into the cup disposal opening. As the cup is disposed, the S/R probe moves to the rinse station and dispenses any aspirated liquid. The tip is then washed and discarded.
4. The gripper moves to the incubator where it checks all 32 incubator positions. If a cup is present, the gripper moves the cup to position 5 on the pipetting station and uses the same procedure listed in step 3 to discard the cup.
5. The S/R probe tip is ejected after all the incubator positions are checked.



Dispense Reagent 1, Reagent 2 and Sample

A TSH sample is present on position 1 of the sample disk.

- A. After preoperation functions are complete, the gripper takes a tip from the tip tray and transports it to position 1 of the pipetting station. The gripper returns to its Stand-by position.
- B. The sample disk rotates until position 1 is in the sampling position.
- C. The S/R probe moves to position 1 of the pipetting station, descends to obtain the tip, rises and returns to its Stand-by position.
- D. During this time, the reagent disk rotates until the TSH reagent pack is at the cap open/close mechanism. The mechanism moves forward and opens the caps on the reagent pack. The disk rotates again to move the TSH reagent to the R1 position.

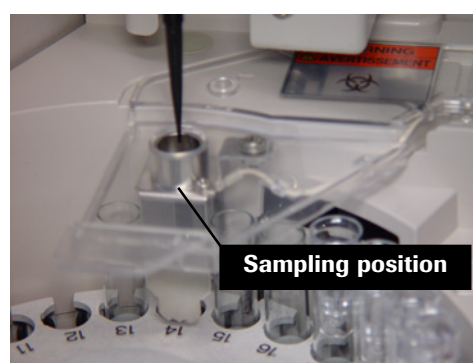
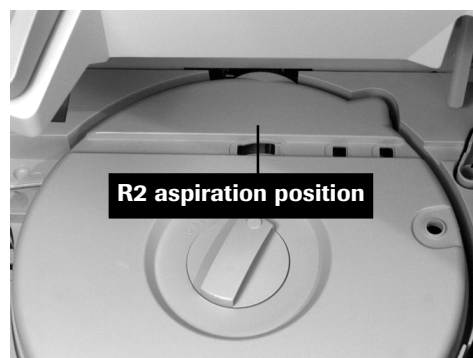
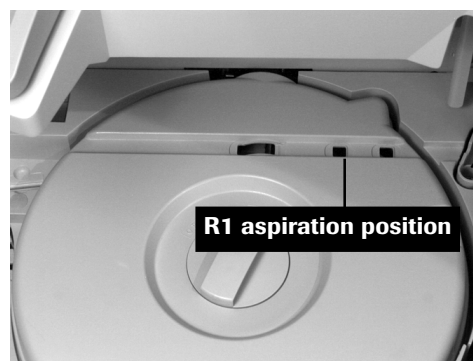
- E. The S/R probe moves from its Stand-by position to the R1 aspiration position. While activating liquid level detection, the probe descends until it is 2 mm below the reagent surface and aspirates 60 μL of R1.



The lowest allowable point the S/R probe can descend to is 1.3 mm above the bottom of the reagent pack.

While aspirating R1, the gripper puts another tip in position 1 of the pipetting station.

- F. If the S/R probe does not detect liquid during descent, no reagent aspiration can occur, an alarm is generated.
- G. After R1 aspiration, the S/R probe rises and moves to the rinse station. To prevent the aspirated R1 from contacting the water in the rinse station, the probe aspirates 10 μL of air. The rinse station externally washes the tip.
- H. During step G, the reagent disk rotates until the TSH reagent pack is in the R2 position.
- I. The S/R probe moves from the rinse station to the R2 position while aspirating another 10 μL of air. This air layer prevents R1 from mixing with R2. While activating liquid level detection, the probe descends until it is 2 mm below the reagent surface and aspirates 50 μL of R2. While aspirating R2 the gripper moves an assay cup to position 5 of the pipetting station.
- J. Upon completion of R2 aspiration, the S/R probe rises and moves to the rinse station. To prevent the aspirated R2 from contacting the water in the rinse station, the probe aspirates another 10 μL of air. The rinse station externally washes the tip.
- K. After R2 aspiration, the reagent disk rotates until the TSH reagent pack is at the cap open/close mechanism. The mechanism moves out and closes the caps.
- L. The S/R probe moves from the rinse station to the sampling position while aspirating another 10 μL of air. While activating liquid level detection, the probe descends until it is 2 mm below the sample surface and aspirates 50 μL of sample. During sample aspiration, clot detection is activated.



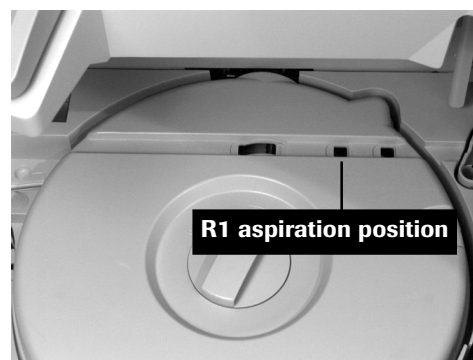
Depending on the sample volumes and the type of vials used (e.g. primary sample tube or sample cup), the sample/reagent (S/R) probe can, when necessary, be lowered further to prevent air being aspirated. With some low capacity vials, the inside diameter is relatively small, which means the level of the liquid sinks when the liquid is being aspirated.

- M. The S/R probe moves from the sampling position to position 5 of the pipetting station. The probe descends until the tip reaches 2 mm below where the calculated level of the reaction mixture surface should be and dispenses the sample, R2 and R1. The probe's downward displacement is determined by calculating the reaction mixture volume for the sample and utilizing downward displacement tables in the software. The probe does not rise during dispense.
- N. After dispense, the S/R probe moves to the tip eject position and ejects the tip.



Dispense Reagent 1, Reagent 2 and Sample

- A TSH sample is present on position 1 of the sample rack.
- After preoperation functions are complete, the gripper takes a tip from the tip tray and transports it to position 1 of the pipetting station. The gripper returns to its Stand-by position.
 - The pusher arm pushes the racks in the A-Line forward to the B-Line. The arm returns to its home position. The first rack loads on the B-Line.
 - As the rack incrementally moves on the B-Line, the rack bar code reader scans all five rack positions and rack ID. When scanning is complete, position 1 of the rack is in the sampling position.
 - The S/R probe moves to position 1 of the pipetting station, descends to obtain the tip, rises and returns to its Stand-by position.
 - During this time, the reagent disk rotates until the TSH reagent pack is at the cap open/close mechanism. The mechanism moves forward and opens the caps on the reagent pack. The disk rotates again to move the TSH reagent to the R1 position.
 - The S/R probe moves from its Stand-by position to the R1 aspiration position. While activating liquid level detection, the probe descends until it is 2 mm below the reagent surface and aspirates 60 μL of R1.

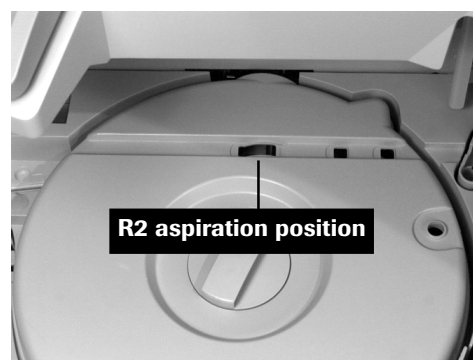


The lowest allowable point the S/R probe can descend to is 1.3 mm above the bottom of the reagent pack.

While aspirating R1, the gripper puts another tip in position 1 of the pipetting station.

- If the S/R probe does not detect liquid during descent, no reagent aspiration can occur, an alarm is generated.
- After R1 aspiration, the S/R probe rises and moves to the rinse station. To prevent the aspirated R1 from contacting the water in the rinse station, the probe aspirates 10 μL of air. The rinse station externally washes the tip.
- During step H, the reagent disk rotates until the TSH reagent pack is in the R2 position.
- The S/R probe moves from the rinse station to the R2 position while aspirating another 10 μL of air. This air layer prevents R1 from mixing with R2. While activating liquid level detection, the probe descends until it is 2 mm below the reagent surface and aspirates 50 μL of R2.

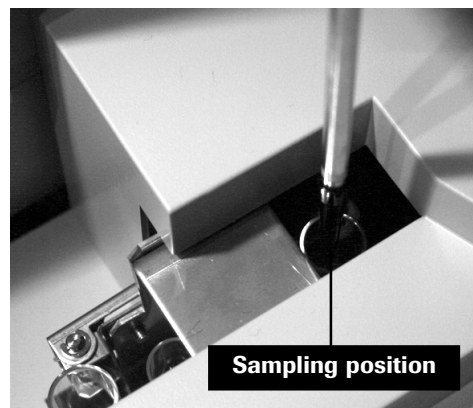
While aspirating R2 the gripper moves an assay cup to position 5 of the pipetting station.



- K. Upon completion of R2 aspiration, the S/R probe rises and moves to the rinse station. To prevent the aspirated R2 from contacting the water in the rinse station, the probe aspirates another 10 μL of air. The rinse station externally washes the tip.
- L. After R2 aspiration, the reagent disk rotates until the TSH reagent pack is at the cap open/close mechanism. The mechanism moves out and closes the caps.
- M. The S/R probe moves from the rinse station to the sampling position while aspirating another 10 μL of air. While activating liquid level detection, the probe descends until it is 2 mm below the sample surface and aspirates 50 μL of sample. During sample aspiration, clot detection is activated.



Depending on the sample volumes and the type of vials used (e.g. primary sample tube or sample cup), the sample/reagent (S/R) probe can, when necessary, be lowered further to prevent air being aspirated. With some low capacity vials, the inside diameter is relatively small, which means the level of the liquid sinks when the liquid is being aspirated.



- N. The S/R probe moves from the sampling position to position 5 of the pipetting station. The probe descends until the tip reaches 2 mm below where the calculated level of the reaction mixture surface should be and dispenses the sample, R2 and R1. The probe's downward displacement is determined by calculating the reaction mixture volume for the sample and utilizing downward displacement tables in the software. The probe does not rise during dispense.
- O. After dispense, the S/R probe moves to the tip eject position and ejects the tip.

First Incubation

- A. The gripper grasps and transports the cup containing the reaction mixture from the pipetting station to the incubator.
- B. The cup is incubated at 37 °C for 9 minutes.
- C. During incubation, the analyzer continues to perform operations for other test(s) or sample(s), if necessary.

Microparticle Preparation

Before the first incubation is completed, the TSH microparticles are mixed to facilitate microparticle aspiration and dispense.

- A. The reagent disk rotates until the TSH reagent pack is at the reagent cap open/close mechanism. The mechanism moves out and opens the cap. The disk moves the reagent pack to the mixing position.

- B. The mixer moves over the reagent disk and descends into the microparticles to a level 1.4 mm above the bottom of the bottle.

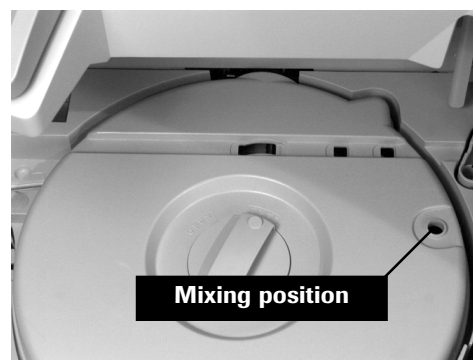


The mixer descends to this level regardless of the volume of microparticles in the bottle.

- C. The mixer stirs the microparticles for 3.7 seconds to obtain a homogeneous suspension.

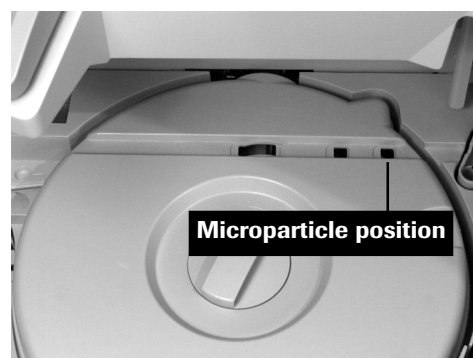
During the mixing, the gripper obtains a fresh assay tip and transports it to position 2 of the pipetting station.

- D. When mixing is complete, the mixer rises and returns to the rinse station where it descends and rotates in the rinse station for washing.
- E. At the same time, the reagent disk rotates the TSH reagent pack to the microparticle pipetting position.



Microparticle Aspiration and Dispense

- A. The gripper grasps the incubating cup and transports it to position 5 of the pipetting station.
- B. The S/R probe moves to the pipetting station and obtains the fresh tip and moves to the microparticle pipetting position.
- C. While activating the liquid level detection, the S/R probe descends to 2 mm below the reagent surface and aspirates 40 µL of microparticles.
- D. After reagent aspiration, the S/R probe rises, moves to position 5 of the pipetting station and descends to dispense the microparticles.
- E. After dispense, the S/R probe descends further until it is 0.8 mm above the bottom of the cup and aspirates the entire volume of reaction mixture. The probe rises while dispensing the reaction mixture back into the cup, thereby mixing the solution and accelerating the reaction in the cup. This mixing takes place only once.
- F. The S/R probe moves to the tip eject position and discards the tip.



Second Incubation

- A. The gripper grasps the cup containing the mixed reaction mixture and returns it to the incubator.
- B. The cup is incubated at 37 °C for 9 minutes.
- C. During incubation, the analyzer continues to perform operations for other test(s) or sample(s), if necessary.

Measurement Process Preparations

Before the second incubation is completed, the sipper probe aspirates ProCell into the measuring cell to facilitate measurement.

- A. The sipper probe moves from its home position to a ProCell bottle and descends to 2 mm below the solution level and aspirates ProCell into the measuring cell. During descent, liquid level detection is activated. The sipper probe can descend as low as 1.3 mm above the bottom of the ProCell bottle.
- B. The sipper probe rises.

Measurement Process

- A. The gripper grasps and transports the cup that has completed its second incubation from the incubator to the aspiration station.
- B. The sipper probe moves to the aspiration station and descends into the cup until it is 0.8 mm above the cup bottom. This descent is independent of the reaction mixture volume.
- C. When the sipper probe detects the reaction mixture in the cup, it aspirates 150 μL .
- D. After aspiration, the sipper probe rises, aspirates 10 μL of air and moves to the sipper rinse station to descend for rinsing.
- E. The gripper grasps the cup from the aspiration station, transports it to the cup disposal opening and discards the cup.
- F. The sipper probe is rinsed.
- G. The sipper probe rises and moves to the ProCell position, descends into the bottle and aspirates ProCell in a set aspiration/dispense sequence. The immune complex is captured by the magnet onto the electrode of the measuring cell. The ProCell washes away all unbound reagent and serum constituents.
- H. After the bound-free separation, a voltage is applied between the working electrode and the counter electrode. The ECL reaction is initiated and measured by the photomultiplier.
- I. After measurement, the sipper probe rises and moves to the CleanCell position and aspirates 20 μL of air. The probe then descends into the CleanCell bottle and aspirates reagent. This procedure is repeated eight times. The alternate flow of air and cleaning solution washes the measuring cell. During this washing process, a voltage is applied between the electrodes, which aids in the cleaning process.
- J. The sipper probe moves to the sipper rinse station, aspirates 20 μL of air and descends into the rinse station for washing.
- K. Finally, the sipper probe rises and moves to the ProCell bottle. The probe descends into the bottle and aspirates 500 μL of ProCell. Next, the probe aspirates 90 μL of ProCell and moves to the rinse station. At the rinse station, the probe dispenses 35 μL to flush the probe and prepare it for the next sample. During the aspirations of the ProCell, a sequence of voltages is applied three times to prepare the electrodes for the next measurement.

One cycle of the measurement process consumes approximately 2 mL each of ProCell and CleanCell.

Signal Detection and Conversion

The measuring cell is kept at a constant 28 °C throughout the measurement process. The photomultiplier tube detects and converts the ECL signal into an electric signal from which the 2010 calculates assay results. For details on this process, refer to Chapter 4, ECL Technology.

Automatic Analyzer Cycles

There are certain analyzer functions that occur automatically while the analyzer is powered ON.

- While in operation, the solid waste tray periodically shakes for 1.5 seconds.
- While in Stand-by, the reagent disk turns 90° every 30 minutes.
- While in Stand-by, the rinse stations for the S/R probe and sipper probe are switched on for 3 seconds every 30 minutes.
- Microparticles undergo a long mix when starting from Stand-by and then every 90 minutes, when pipetting not yet started.
- Microparticles undergo a short mix (3.8 seconds) and then a short mix every 60 minutes for each reagent pack.

3.3 Dilution Steps

The following is a description of how an assay with a dilution is performed, including the number of assay tips and assay cups used in the process.

Assay With One Step Dilution (1:2, 1:5, 1:10)

Tip 1 → diluent (wash)* + sample → cup 1
Tip 2 → R1 (wash)* + R2 (wash)* → cup 2 ... 1st incubation
+ diluted sample from cup 1
Tip 3 → M (wash)* → cup 2 ... 2nd incubation
Detection

* (wash) = the outside of the assay tip is washed.

R1 = Reagent 1

R2 = Reagent 2

M = Microparticles

Assay With Two Step Dilution (1:50, 1:100)

Tip 1 → diluent (wash)* + sample → cup 1
Tip 2 → diluent (wash)* → cup 2
+ diluted sample from cup 1
Tip 3 → R1 (wash)* + R2 (wash)* → cup 3 ... 1st incubation
+ diluted sample from cup 2
Tip 4 → M (wash)* → cup 3 ... 2nd incubation
Detection

* (wash) = the outside of the assay tip is washed.

R1 = Reagent 1

R2 = Reagent 2

M = Microparticles

Pretreatment Steps

In certain test protocols, pretreatment reagent is added prior to R1, R2 or M.

Pretreatment Assay

Tip 1 → PT1 (wash)* + PT2 (wash)* → cup 1 ... 1st incubation
+ sample
Tip 2 → R1 + pretreated sample in cup 1 → cup 1 ... 2nd incubation
Tip 3 → M (wash)* + R2 → cup 1 ... 3rd incubation
+ reaction mixture in cup 1
Detection

* (wash) = the outside of the assay tip is washed.

PT1 = Pretreatment 1

PT2 = Pretreatment 2

R1 = Reagent 1

R2 = Reagent 2

M = Microparticles

3.4 Analyzer Status Conditions

The 2010 analyzer can occupy a number of status conditions. A table of the status conditions you normally see during routine operation or maintenance procedures is listed below. There are several other conditions that exist; however, most of these status conditions are seen during various adjustment or maintenance procedures performed by a Roche Diagnostics representative. These additional status conditions are not included in the table below.



A. Stop (Analyzer Stop)

The analyzer is no longer able to continue operation. An alarm was issued. Take the appropriate measures to resolve the problem. For further details on A. Stop, refer to Chapter 3, Instrument Alarms – User's Guide.



A. Stop/L. Stop (Analyzer Stop/Line Stop)

The analyzer is already in A. Stop status when the lines stop operation. For further details on A. Stop and L. Stop, refer to Chapter 3, Instrument Alarms – User's Guide.



A. Stop/R. Stop (Analyzer Stop/Rack Stop)

The analyzer is already in A. Stop status when the A-Line stops supplying racks to the B-Line. For further details on A. Stop and R. Stop, refer to Chapter 3, Instrument Alarms – User's Guide.

BC card scan

This status is seen when a bar code card scan is initiated from the **CONTROL DEFINITION** or **CALIBRATION DATA** screens.

E. Stop (Emergency Stop)

An emergency stop condition exists. An alarm was issued. Take the appropriate measures to resolve the problem. For further details on E. Stop, refer to Chapter 3, Instrument Alarms – User's Guide.

FD Access

This status occurs when a floppy disk (FD) reading/writing utility is initiated from the **MAINTENANCE** screen.

FDD cleaning

This status occurs when a floppy disk drive (FDD) cleaning is initiated from the **MAINTENANCE** screen.

Finalization

The status of the analyzer when it is between the status conditions S. Stop and Stand-by.

Finalization maint.

This status occurs when Finalization Maintenance is initiated from the **MAINTENANCE** screen.

Initialization

This status is seen when the 2010 is powered ON or when **START** is pressed from Stand-by.



L. & A. reset all (Line & Analyzer)

L. and A. reset all status occurs when the corresponding function is initiated from the **MAINTENANCE** screen. This function resets the analyzer and the lines.



L. Stop (Line Stop)

All lines stop operation. An alarm was issued. Take the appropriate measures to resolve the problem. For further details on L. Stop, refer to Chapter 3, Instrument Alarms – User's Guide.

Liquid flow cleaning

Liquid flow cleaning occurs when this function is initiated from the **MAINTENANCE** screen.

M. Cell preparation

Measuring cell (M. Cell) preparation occurs when this function is initiated from the **MAINTENANCE** screen.

Operation

This is the status during which the 2010 performs its routine operations.

P. Stop (Partial Stop)

A partial stop condition exists. An alarm was issued. Take the appropriate measures to resolve the problem. For further details on P. Stop, refer to Chapter 3, Instrument Alarms – User's Guide.



R. Stop (Rack Stop)

This status occurs when there are no more racks to process on the A-Line or B-Line.



Rack clear

Rack clear status occurs when the corresponding function is initiated from the **MAINTENANCE** screen. This function clears any remaining racks on the A-, B- or C-Lines.

Reagent scan

This status is seen when a reagent scan is initiated from the **INVENTORY** screen.

S/R pipettor prime

This status occurs when the S/R pipettor prime is initiated from the **MAINTENANCE** screen.

S/R probe LLD volt.

This status is seen when the analyzer is monitoring the liquid level detection voltage of the S/R probe. The check is initiated from the **VOLTAGE MONITOR** screen (**UTILITY**) folder.

**S. Stop (Sampling Stop)**

This status occurs when **SMPL. STOP** is pressed or when sampling is complete.

**S. Stop-S. Scan**

The analyzer is in S. Stop and a sample scan is requested from the **STATUS** screen, or S is pressed while the analyzer is in S. Stop.

**Sample scan**

This status occurs when a sample scan is initiated from the **STATUS** screen.

Sipper LLD volt.

The analyzer is monitoring the liquid level detection voltage of the sipper probe. The check is initiated from the **VOLTAGE MONITOR** screen (**UTILITY**) folder.

Sipper pipet. prime

This status occurs when the sipper pipettor prime is initiated from the **MAINTENANCE** screen.

Stand-by

The analyzer is not performing any operations.

Stop

This status occurs when **STOP** is pressed or when a Stop alarm condition exists. If an alarm exists, take the appropriate measures to resolve the problem. For further details on Stop, refer to Chapter 3, Instrument Alarms – User's Guide.

System reset

A system reset is initiated from the **MAINTENANCE** screen.

4. ECL Technology

4.1 Introduction

The last years have seen the development and refinement of many new immunoassay measurement principles and systems. The major trend has been away from liquid phase assays with radioisotopic labels, and towards fast solid-phase assays based on monoclonal antibodies. This development is moving further towards precise and reliable non-isotopic, automated or semi-automated laboratory assays with detection limits measured in the picomolar (10^{-12}) and attomolar (10^{-18}) range.

ECL Assay Principles

Electrochemiluminescent (ECL) processes are known to occur with numerous molecules including compounds of ruthenium, osmium, rhenium or other elements.

ECL is a process in which highly reactive species are generated from stable precursors at the surface of an electrode. These highly reactive species react with one another, producing light.

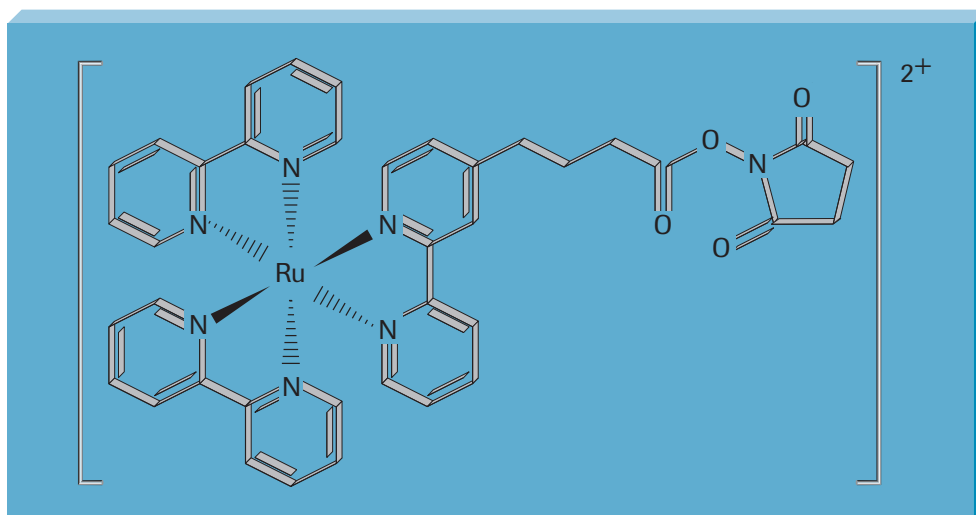
The development of ECL/Origen immunoassays is based on the use of a ruthenium(II)-tris(bipyridyl) $[\text{Ru}(\text{bpy})_3]^{2+}$ complex and tripropylamine (TPA). The final chemiluminescent product is formed during the detection step.

The chemiluminescent reactions that lead to the emission of light from the ruthenium complex are initiated electrically, rather than chemically. This is achieved by applying a voltage to the immunological complexes (including the ruthenium complex) that are attached to streptavidin-coated microparticles. The advantage of electrically initiating the chemiluminescent reaction is that the entire reaction can be precisely controlled.

Use of the Ruthenium Complex

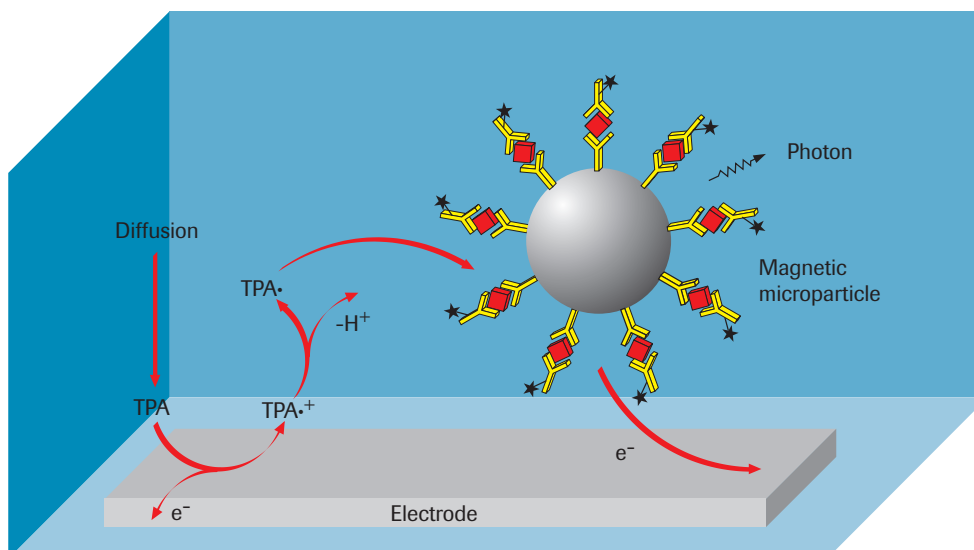
ECL technology uses a ruthenium chelate as the complex for the development of light. Salts of ruthenium-tris(bipyridyl) are stable, water-soluble compounds. The bipyridyl ligands can be readily modified with reactive groups to form activated chemiluminescent compounds.

For the development of ECL immunoassays, a N-hydroxysuccinimide (NHS) ester of a modified $\text{Ru}(\text{bpy})_3$ complex is used because it can be easily coupled with amino groups of proteins, haptens and nucleic acids. This allows the detection technology to be applied to a wide variety of analytes.



The ruthenium complex

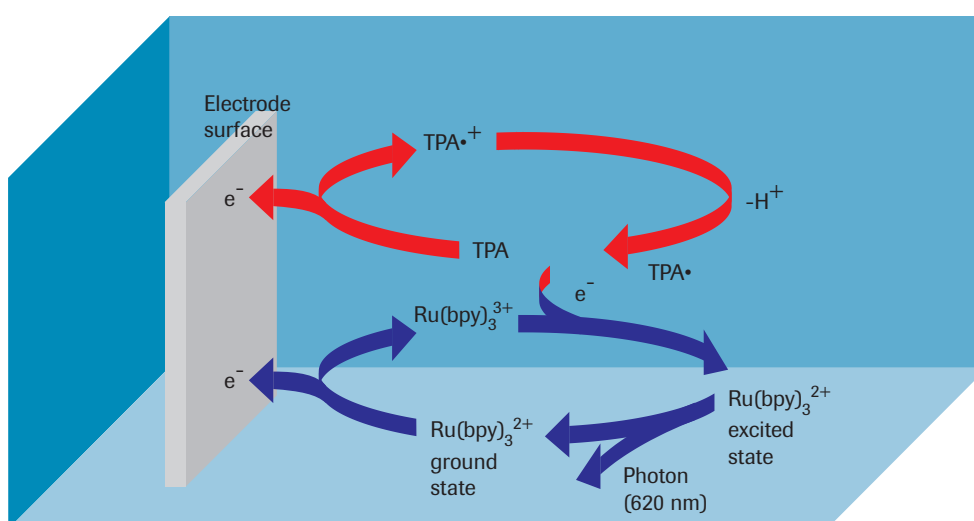
The ECL Reaction at the Electrode Surface



Detection of a ruthenium-labeled immune complex

Two electrochemically active substances, the ruthenium complex and tripropylamine (TPA), are involved in the reactions that lead to the emission of light. Both substances remain stable, as long as a voltage is not applied.

The ECL reaction of ruthenium-tris(bipyridyl)²⁺ and tripropylamine occurs at the surface of a platinum electrode. The applied voltage creates an electrical field, which causes all the materials in this field to react. Tripropylamine is oxidized at the electrode, releases an electron and forms an intermediate tripropylamine radical-cation, which further reacts by releasing a proton (H⁺) to form a TPA radical (TPA•). In turn, the ruthenium complex also releases an electron at the surface of the electrode thus oxidizing to form the Ru(bpy)₃³⁺ cation. This ruthenium cation is the second reaction component for the following chemiluminescent reaction with the TPA radical.



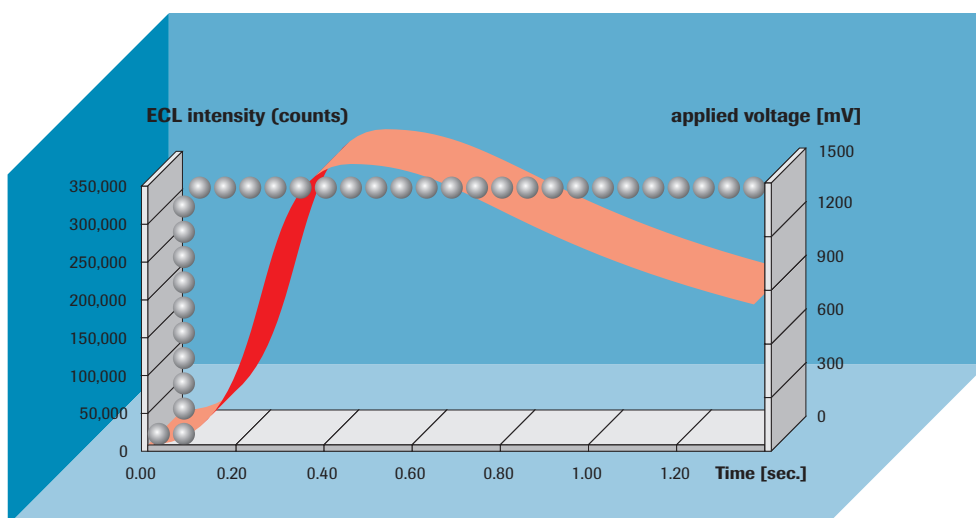
The ECL reaction at the electrode surface

TPA• and $\text{Ru}(\text{bpy})_3^{3+}$ react with one another, whereby $\text{Ru}(\text{bpy})_3^{3+}$ is reduced to $\text{Ru}(\text{bpy})_3^{2+}$ and at the same time forms an excited state via energy transfer. This excited state is unstable and decays with emission of a photon at 620 nm to its original state. The reaction cycle can now start again. The tripropylamine radical reduces to by-products which do not affect the chemiluminescence process. TPA is used up and therefore must be present in excess. The reaction is controlled by diffusion of the TPA and the amount of ruthenium complex present. As TPA in the electrical field is depleted, the signal strength (light) is slowly reduced once the maximum is reached.

Although during measurement, TPA is used up, the ruthenium ground state complex is continually regenerated. This means that the ruthenium complex can perform many light-generating cycles during the measurement process, therefore showing an inherent amplification effect which contributes to the technology's sensitivity. Many photons can be created from one antigen-antibody complex.

ECL Signal Generation

The graph displays a typical ECL signal generation. Viewed from an electrical perspective, the reaction can be explained as follows: When a voltage is applied to the detection cell electrode, a peak of light emission occurs over a short time interval and can be detected as the resulting ECL signal. A defined area under the curve is measured around the intensity maximum.



ECL signal generation

The dotted line indicates the voltage at the electrode used to generate the ECL signal. The solid line is the actual light output measured by the photomultiplier detector.

ECL Measuring Cell

The core of the system is the ECL detection cell, which is designed as a flow-through cell. Essentially, three operating steps are performed in the measuring cell:

- **Bound/Free Separation**

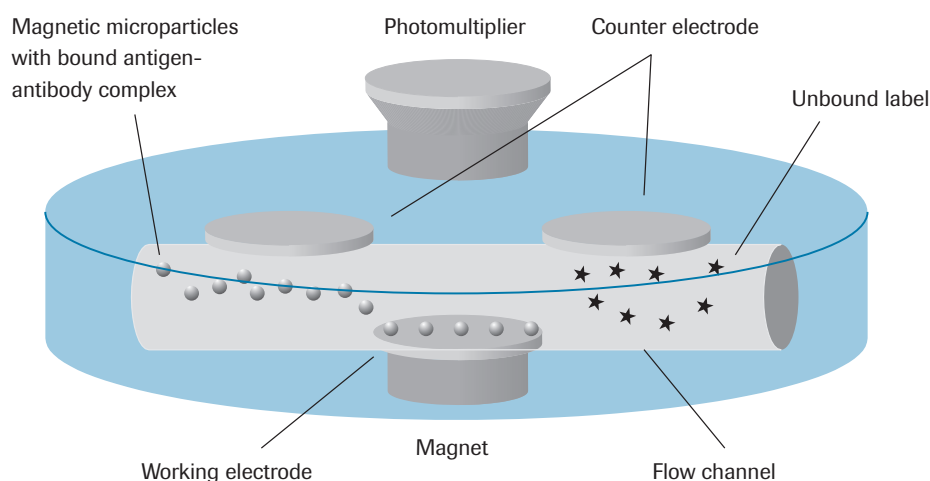
Using a magnet, the streptavidin microparticles that are coated with antigen-antibody complexes, are uniformly deposited on the working electrode. A system buffer (ProCell) is used to wash the particles on the working electrode and to flush out the excess reagent and sample materials from the measuring cell.

- **ECL Reaction**

The magnet is removed and a voltage is then applied to the electrode on which the microparticles, coated with antigen-antibody complexes, are deposited to initiate the ECL reaction. The light emission is measured with a photomultiplier. The system then uses the corresponding signals for the calculation of results.

- **Release of Microparticles and Cell Cleaning**

Once the measurement is completed, the paramagnetic microparticles are washed away from the electrode surface with a special cleaning solution (CleanCell). The surface of the measuring cell is regenerated by varying the potential on the electrode. The cell is then ready for another measurement.

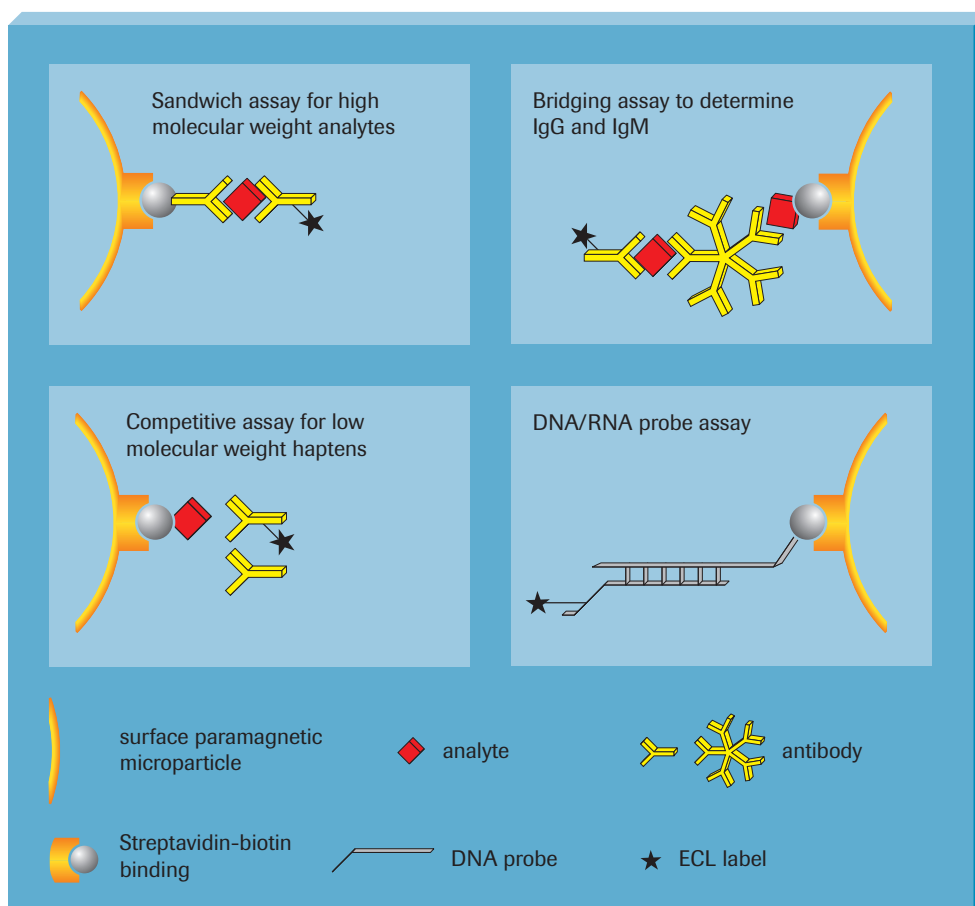


ECL measuring cell

Advantages of ECL Technology

Electrochemiluminescence is a highly innovative technology that offers distinct advantages over other detection techniques.

- Extremely stable non-isotopic label allows liquid reagent convenience.
- Enhanced sensitivity in combination with short incubation times means high quality assays and fast result turnaround.
- Large measuring range of five orders of magnitude minimizes dilutions and repeats, reducing handling time and reagent costs.
- Applicable for the detection of all analytes providing a solid platform for menu expansion.



ECL assay types

5. Test Principles

5.1 Competitive Test Principle

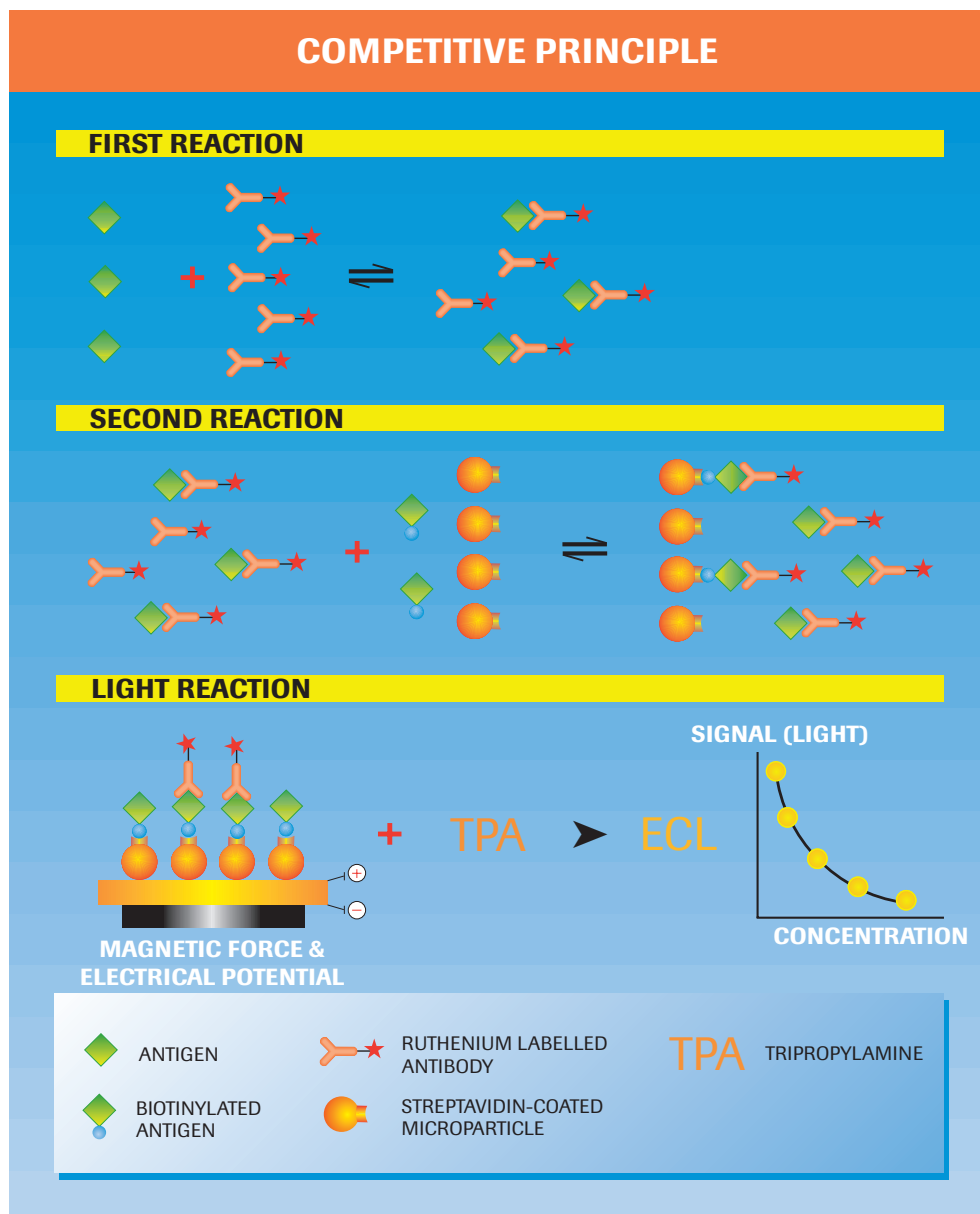
Three test principles are available on the Elecsys 2010 Immunoassay System: Competitive principle for extremely small analytes, sandwich principle (one or two steps) for larger analytes and a bridging principle to detect antibodies in the sample.

5.2 Competitive Principle

This principle is applied to analytes of low molecular weight, such as FT3.

- In the first step, sample and a specific anti-T3 antibody labeled with a ruthenium complex are combined in an assay cup.
- After the first incubation, biotinylated T3 and streptavidin-coated paramagnetic microparticles are added. The still free binding sites of the labeled antibody become occupied, with formation of an antibody-hapten complex. The entire complex is bound to the microparticle via interaction of biotin and streptavidin.
- After the second incubation, the reaction mixture containing the immune complexes is transported into the measuring cell. The immune complexes are magnetically entrapped on the working electrode, but unbound reagent and sample are washed away by ProCell.
- In the ECL reaction, the conjugate is a ruthenium based derivative and the chemiluminescent reaction is electrically stimulated to produce light. The amount of light produced is indirectly proportional to the amount of antigen in the patient sample.

Evaluation and calculation of concentration of the antigen are carried out by means of a calibration curve that was established using standards of known antigen concentration.



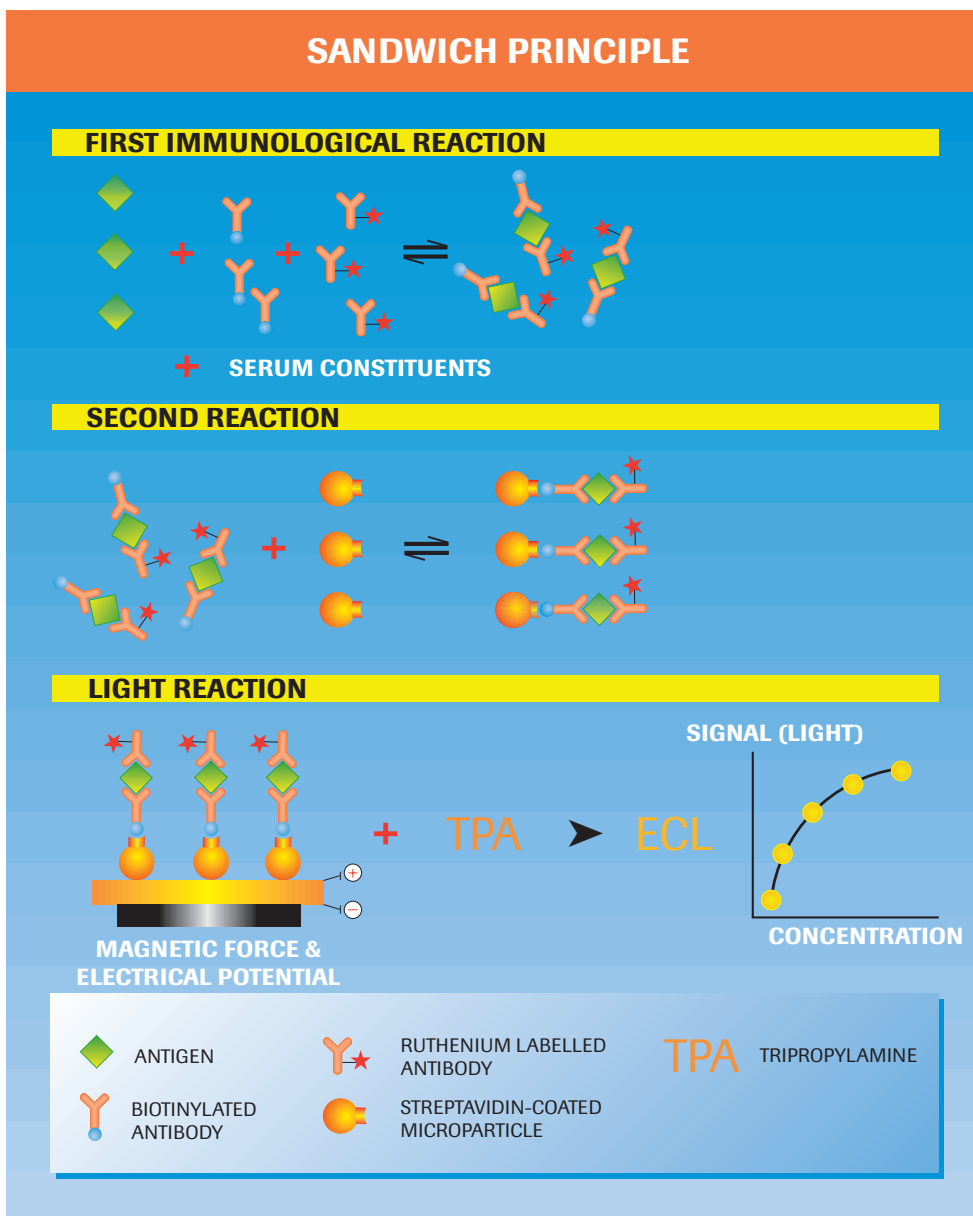
Competitive principle

5.3 Sandwich Principle

The sandwich principle is applied to higher molecular weight analytes, such as thyroid-stimulating hormone (TSH).

- In the first step, patient sample is combined with a reagent containing biotinylated TSH antibody and a ruthenium-labeled TSH-specific antibody in an assay cup. During a nine-minute incubation step, antibodies capture the TSH present in the sample.
- In the second step, streptavidin-coated paramagnetic microparticles are added. During a second nine-minute incubation, the biotinylated antibody attaches to the streptavidin-coated surface of the microparticles.
- After the second incubation, the reaction mixture containing the immune complexes is transported into the measuring cell; the immune complexes are magnetically entrapped on the working electrode, but unbound reagent and sample are washed away by ProCell.
- In the ECL reaction, the conjugate is a ruthenium based derivative and the chemiluminescent reaction is electrically stimulated to produce light. The amount of light produced is directly proportional to the amount of TSH in the sample.

Evaluation and calculation of concentration of the antigen or analyte are carried out by means of a calibration curve that was established using standards of known antigen concentration.



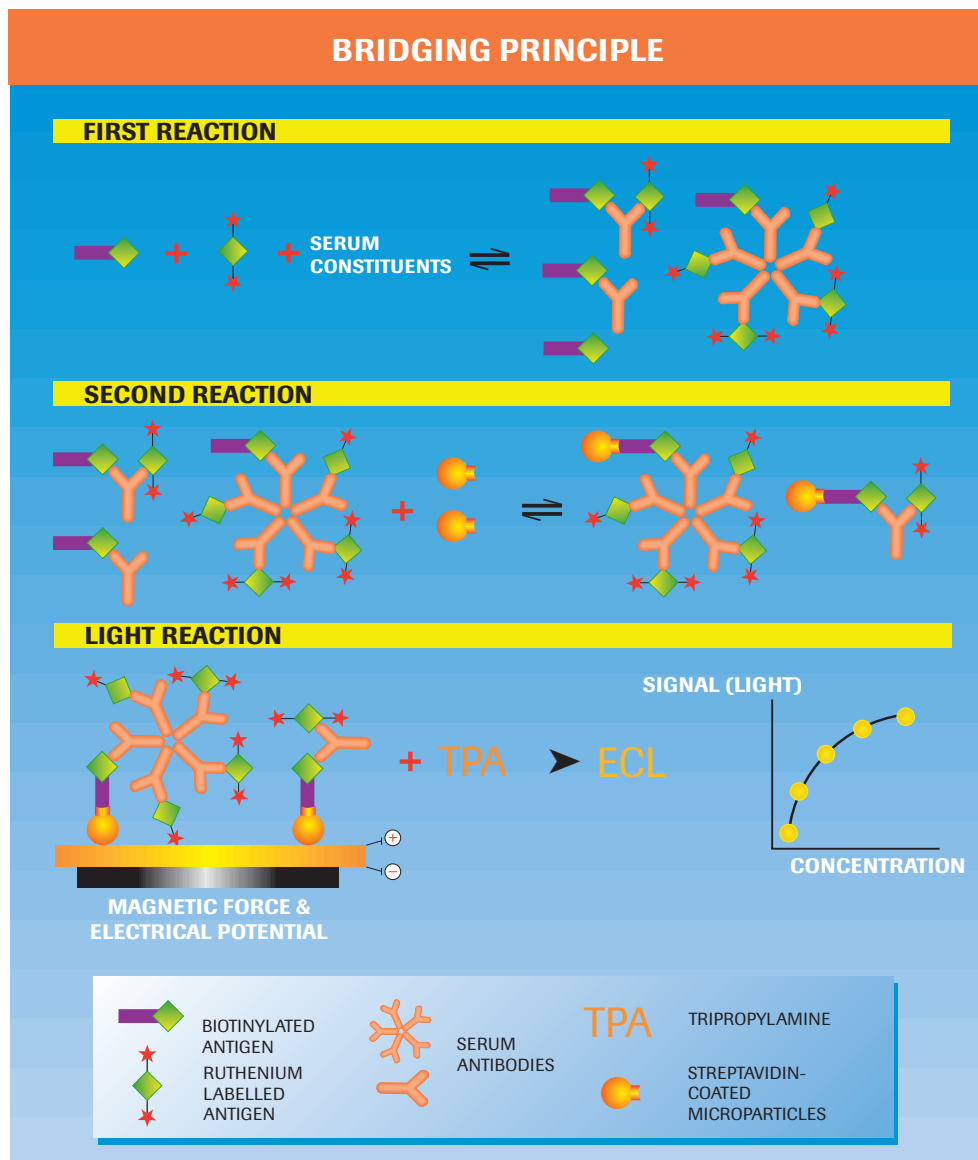
Sandwich principle

5.4 Bridging Principle

The bridging principle is similar to the sandwich principle, except that the assay is designed to detect antibodies, not antigens, (e.g., IgG, IgM and IgA). This is accomplished by including biotinylated and ruthenium-labeled antigens in the reagents for which the targeted antibody has affinity.

- In the first step, serum antibodies bind with the biotinylated and ruthenium-labeled antigens to form an immune complex.
- The immune complex then reacts with streptavidin-coated microparticles via the biotinylated antigen.
- After the second incubation, the reaction mixture containing the immune complexes is transported into the measuring cell; the immune complexes are magnetically entrapped on the working electrode, but unbound reagent and sample are washed away by ProCell.
- In the ECL reaction, the conjugate is a ruthenium based derivative and the chemiluminescent reaction is electrically stimulated to produce light. The amount of light produced is directly proportional to the amount of analyte in the sample.

Evaluation and calculation of the concentration of the antibody are carried out by means of a calibration curve that was established using standards of known antibody concentrations.

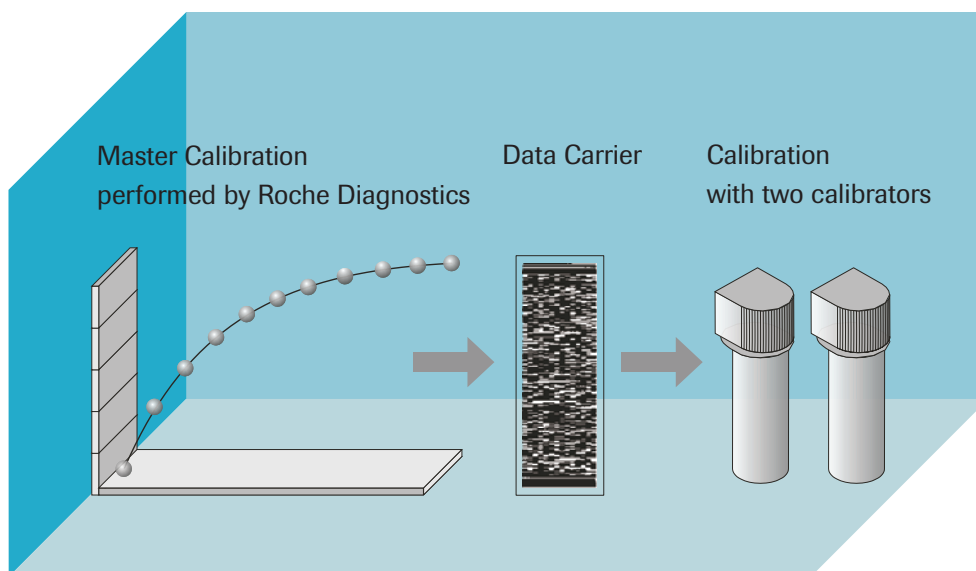


Bridging principle

6. Calibration

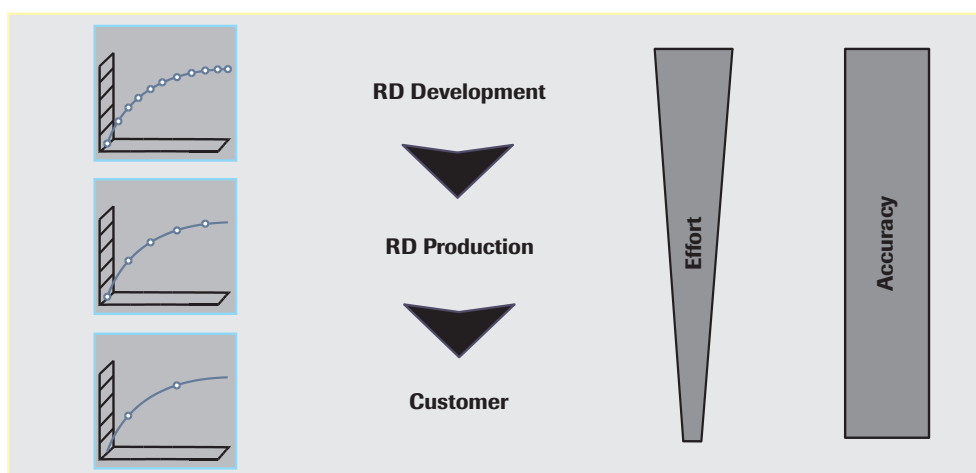
6.1 Reagent Calibration

Calibration is required to determine the concentration of an unknown substance as accurately as possible independent of reagent lot, reagent conditions, and analyzer conditions. For this, a master calibration curve is generated at Roche Diagnostics during production of the reagent that is encoded in the 2D bar code of the appropriate reagent pack. This information is then transferred to the analyzer. At the customer site, the analyzer generates an update of the master curve by measuring two calibrators under routine laboratory conditions.



The calibration curve produced from the bar-coded master calibration and the measured calibration is specific to each reagent lot and in some cases, to an individual reagent pack. The result of a calibration is validated automatically by the analyzer and can be further validated by the operator.

Master Calibration



Calibration concept of the Elecsys 2010

A reference standardization curve utilizing master test kit reagents and certified reference standard material [e.g., World Health Organization (WHO) reference material] is measured at Roche Diagnostics. This curve uses 10 to 12 points ($n=10$ to 12). The reference standard curve is the basis for the production of master calibrators.

A lot-specific master calibration curve ($n=5$ or 6) is measured at Roche Diagnostics using lot-specific test kit reagents and master calibrators. The shape of the lot-specific master curve is characterized by a four-parameter Rodbard function. The data characterizing this curve is stored in the lot-specific reagent bar code. Lot-specific calibrator assigned values (i.e., CalSet assigned values) are read off the lot-specific master calibration curve and are encoded in the CalSet calibrator bar code card.

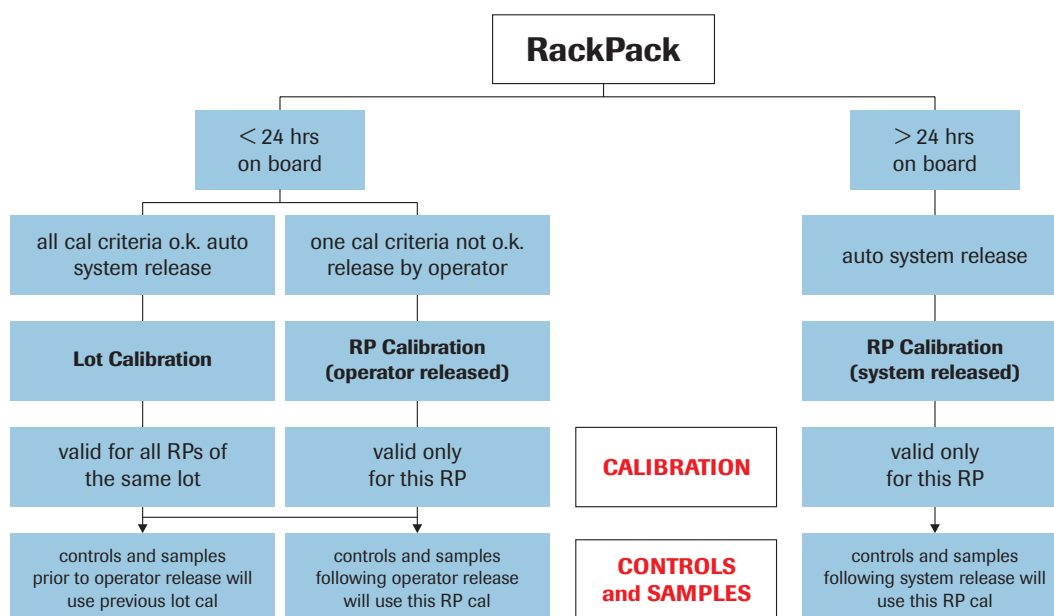
At the customer site, the calibration results from two calibrators that were measured under routine conditions are mathematically combined with the encoded data from the 2D bar code. From this combination, the Elecsys 2010 determines a lot calibration or reagent pack calibration from which the concentration of measured samples is reliably calculated.

Lot Calibration

A lot calibration (L-Cal) is a calibration performed with a fresh reagent pack that has not been on the analyzer longer than 24 hours. Reagent-specific calibrators are used to update two of the four Rodbard curve-defining parameters. This adjusts the curve to match the original lot-specific calibration curve. The lot calibration is valid for all other reagent packs of the same lot, provided these reagent packs were stored as specified in the package insert and not on the analyzer longer than 7 days.

Reagent Pack Calibration

A reagent pack calibration (R-Cal) is performed with a reagent that has been on the analyzer more than 24 hours or is generated by an operator-released calibration. A reagent pack calibration is valid for one specific reagent pack only. The reagent pack calibration is compared to the most recent stored L-Cal for validation.



Lot and RackPack calibration

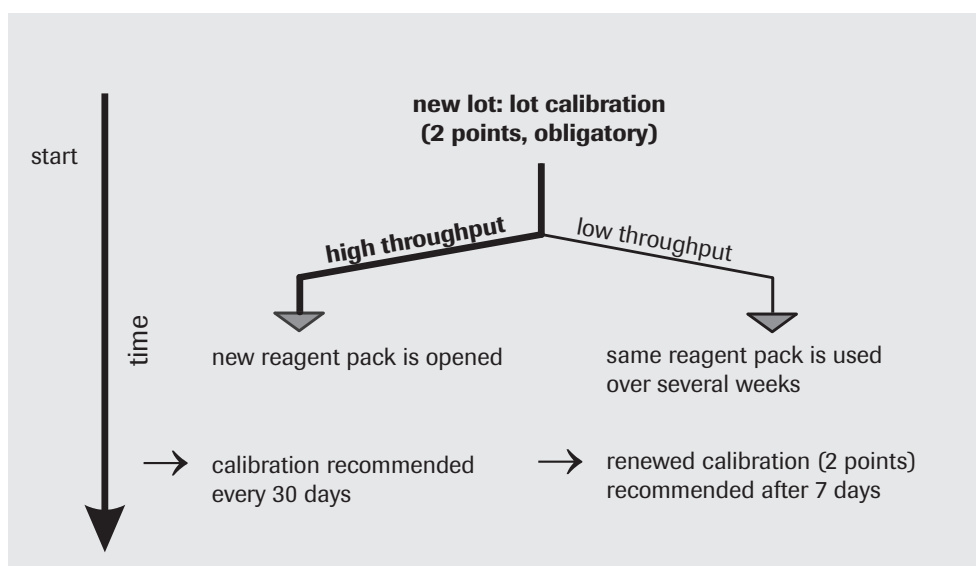
Calibration Stability

The stability of calibration is determined by two factors:

- the long term stability of the instrumentation
- the age of the reagent

For many assays, a reagent pack will be used within seven days. In this situation, it is not necessary to renew the calibration for the new reagent pack. In this case, the lot calibration can be used for all other new reagent packs for a period as recommended in the package insert (refer to the Calibration Frequency section). After that period, a new lot calibration is recommended.

If the reagent is kept on the analyzer for more than seven days, it is recommended to renew the calibration. This renewal of the calibration can be repeated as needed until the on-analyzer open stability of the reagent is exceeded (e.g., two months).



Calibration workflow on the Elecsys 2010

Calibration Assessment and Quality Criteria

The status of a calibration is displayed in the **CALIBRATION** screen (**UTILITY** folder) and is printed with the reports. Colored buttons enable an easy assessment of the calibration status. For a detailed description of calibration statuses and quality criteria, please refer to Chapters 7 and 8 in the Software Guide.

6.2 Calibration of Quantitative Assays

The following is a description of the different methods utilized by the Elecsys 2010 analyzer for calculating results. To calculate quantitative tests, the 2010 utilizes the following three calibration functions to convert measured signals into concentrations:

- Rodbard function
- linear calibration function
- linear-reciprocal calibration function

The calibration function used by the system is encoded in the 2-dimensional bar code on the appropriate reagent pack. The calculations are performed automatically by the analyzer, including the correction for samples diluted by the analyzer.

Rodbard Function

The conversion of the measured signal into a concentration using the Rodbard function is as follows:

$$y = \frac{a - d}{1 + \left(\frac{x}{b}\right)^c} + d$$

x = Sample concentration
 a, b, c, d = Rodbard function parameters
 y = Signal

Parameters b and c define the shape of the curve and parameters a and d define the position of the curve. Under the controlled conditions of automation on the analyzer, the shape of the calibration curve is very stable and, therefore, it is possible to calibrate this nonlinear function with only two calibrators and the information of the shape parameters b and c . The curve position parameters a and d are calculated with each calibration. Such a calibration is called 2-point calibration.

The following inverse formula is used to determine the unknown's concentration based on its signal.

$$x = b \cdot \left(\frac{a - y}{y - d}\right)^{\frac{1}{c}}$$

y = Signal
 a, b, c, d = Rodbard function parameters
 x = Sample concentration

Linear Calibration Function

The conversion of the measured signal into a concentration is as follows:

$$y = b \cdot x + a$$

y = Signal
 x = Concentration
 a, b = Calibration curve parameters
 (y-intercept and slope)

Calibrations using a linear calibration curve are always performed using two calibrators.

The following inverse formula is used to determine the unknown's concentration based on its signal.

$$x = \frac{y - a}{b}$$

x = Sample concentration
 a, b = Calibration curve parameters
 y = Signal

Linear Reciprocal Calibration Function

The conversion of the measured signal into a concentration is as follows:

$$\frac{1}{y} = b \cdot x + a$$

y = Signal

x = Concentration

a, b = Calibration curve parameters
(y-intercept and slope)

Calibrations using a linear reciprocal calibration curve are always performed using two calibrators.

The following inverse formula is used to determine the unknown's concentration based on its signal.

$$x = \frac{1 - a \cdot y}{b \cdot y}$$

x = Sample concentration

a, b = Calibration curve parameters

y = Signal

6.3 Calibration of Qualitative Assays

In order to assess patient samples as reactive, non-reactive or borderline, a so-called cutoff value S_{Cutoff} is calculated.

Two calibrators, reactive (REAC) and non-reactive (N-REAC), are used for calibration. These calibrators produce effective signals S_{POS} and S_{NEG} from which the cutoff value is calculated as follows.

$$S_{\text{Cutoff}} = (A \cdot S_{\text{NEG}}) + (B \cdot S_{\text{POS}}) + C$$

S_{Cutoff} = Cutoff value

S_{POS} = Effective signal of the reactive calibrator

S_{NEG} = Effective signal of the non-reactive calibrator

A, B, C = Assay specific cutoff parameters
(according to the 2D bar code)

Two cutoff indices $\text{Cutoff}_{\text{IndexPOS}}$ and $\text{Cutoff}_{\text{IndexNEG}}$ are calculated using the two calibrators as follows.

$$\text{Cutoff}_{\text{IndexNEG}} = \frac{S_{\text{NEG}}}{S_{\text{Cutoff}}}$$

$\text{Cutoff}_{\text{IndexPOS}}$ = Cutoff index of the reactive calibrator

$\text{Cutoff}_{\text{IndexNEG}}$ = Cutoff index of the non-reactive calibrator

$$\text{Cutoff}_{\text{IndexPOS}} = \frac{S_{\text{POS}}}{S_{\text{Cutoff}}}$$

S_{POS} = Effective signal of the reactive calibrator

S_{NEG} = Effective signal of the non-reactive calibrator

S_{Cutoff} = Cutoff value of the calibrator

Both cutoff indices are used to check the quality of the calibration.

The calibration status is made up of the following parameters:

- Cutoff value S_{Cutoff}
- Cutoff indices of both calibrators REAC and N-REAC.

Calibrations for qualitative tests are always performed using both reactive and non-reactive calibrators.

Result Calculation for Qualitative Assays

In order to calculate the result of a qualitative assay (cutoff test), Elecsys 2010 compares the effective signal of the measurement S_{eff} with the cutoff signal of the calibration S_{Cutoff} . For that purpose, a cutoff index $\text{Cutoff}_{\text{Index}}$ is calculated as the ratio between the effective signal and the cutoff signal as follows.

$$\text{Cutoff}_{\text{Index}} = \frac{S_{\text{eff}}}{S_{\text{Cutoff}}}$$

If the effective signal of the measurement S_{eff} equals the cutoff signal of the calibration S_{Cutoff} , the cutoff index $\text{Cutoff}_{\text{Index}}$ equals 1. For effective signals being lower or higher than the cutoff signal, the cutoff index is smaller or larger than 1, respectively.

In order to evaluate the reactivity of a sample, the 2D barcode contains defined limit values. If the cutoff indices, which were calculated from the effective signals, lie between the lower limit (LL) and the upper limit (UL), no decision can be made regarding the reactivity or non-reactivity of the sample (borderline).

The test result is evaluated as follows, depending on the test principle (sandwich tests show a positive slope, competitive tests exhibit a negative slope).

Result	Sandwich Test (positive slope)	Competitive Test (negative slope)
reactive	$\text{Cutoff}_{\text{Index}} \geq \text{UL}$	$\text{Cutoff}_{\text{Index}} \leq \text{LL}$
non-reactive	$\text{Cutoff}_{\text{Index}} < \text{LL}$	$\text{Cutoff}_{\text{Index}} > \text{UL}$
borderline	$\text{LL} \leq \text{Cutoff}_{\text{Index}} < \text{UL}$	$\text{LL} < \text{Cutoff}_{\text{Index}} \leq \text{UL}$

**Elecsys 2010
Software Guide**

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1. Operating Basics

1.1 Introduction

The software guide describes the software screens. Each screen is illustrated and explained in the manual. This chapter provides instructions on how to use the manual and fundamental operations of the software.



Disk



Rack

The above symbols are illustrated next to field or screen explanations to indicate differences between analyzers with a sample rack system and those with sample disk system.

1.2 The Screen

Screen Configuration

Status line

ON/OFF button

Command button

Stand-by
Operator ID: 47 07:40

Inventory	Orders	Results	QC	Status	Utility
-----------	--------	---------	----	--------	---------

Sample ID :

Sequence No. : 200

Disk - Pos. : 1 -

Sample volume : ul

Pre-dil. Off

Select Control

Position Search

Dilution Factor

Sample Cup Normal

Sample Control Calibrator

Register

TSH 0	T4 1	T3 0	HCGSTAT 0	CEA 1
AFP 1	PSA 1	FERR 0	B12 0	P-B12
FOL 0	DIG 0			

Many functions can be started via touch-sensitive buttons on the touchscreen. Please observe: the buttons should be "touched" and **not** "pressed" for long periods.

Screen Buttons

Screens have screen buttons available with which you can access other screens: **INVENTORY**, **ORDERS**, **RESULTS**, **QC**, **STATUS** and **UTILITY**. In most screens you can access pop-up windows, again by touching screen buttons.

You can initiate an action by touching a button, for example, to select a test.

The button colors and/or the text colors change after the button is touched, and indicates if the function has been activated. The button colors and their meanings are dependent upon the screen displayed. Usually, buttons depicting activated functions are light blue, buttons depicting non-activated functions are green. Further colors (yellow, red, white) indicate the status of a test or sample.

The buttons have differing functions.

1-2

Roche Diagnostics Elecsys® 2010 Immunoassay System – A4 Format Software Guide V 4.0.

Command buttons

Most buttons have been assigned task-oriented functions. Examples: you can select a test by touching the relevant test button on the **ORDERS** screen, and scan in the bar codes from the sample tubes by touching the Scan Samples button on the **STATUS** screen.

ON/OFF buttons

The function is activated if the word ON is displayed in the button. The function is deactivated by touching the button, the button display changes to OFF. Example: the Pre-Dilution button on the **ORDERS** menu, the user chooses to dilute the sample when ON is displayed.

Close, Cancel and OK buttons

These buttons **always** have the same functions in all screens and windows.

- Close Closes the screen or window.
- Cancel Cancels an action; a window is closed; any entries made are not saved.
- OK An action will be accepted; a window is closed, the action will be initiated



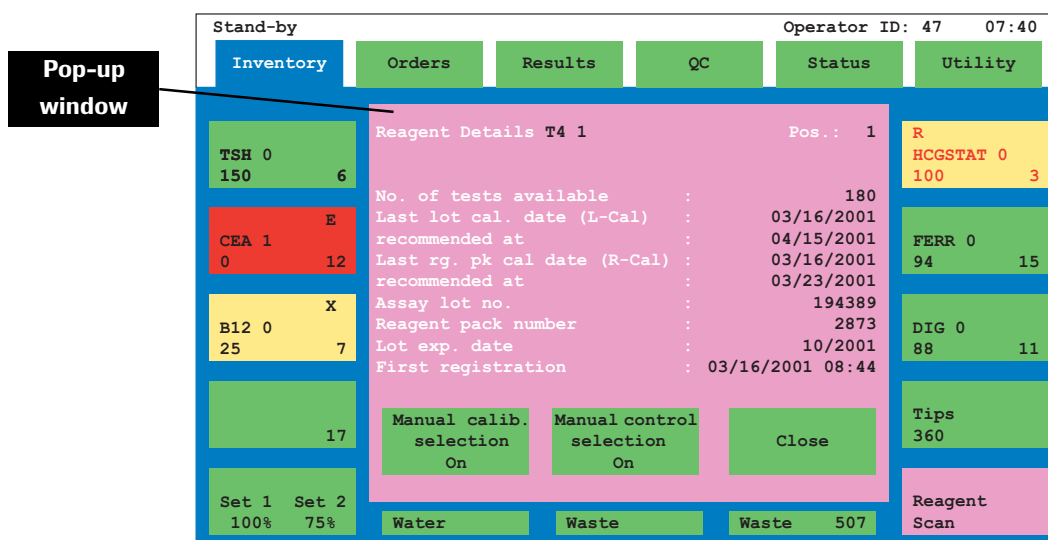
The Close, Cancel and OK buttons will only be described in the individual chapters of the Software Guide when their use is of special importance.

Status Line

The status line displays the operator ID, the system status and the actual time. If an alarm occurs, the color of the status line changes. The identity number displayed on the status line refers to the user currently registered with the analyzer. The system status indicates the current status of the analyzer.

Pop-up Windows

Pop-up windows are opened by touching screen buttons within opened screens. Pop-up windows contain additional context-specific information and, where required, further screen buttons with which you can initiate further actions.



Data Fields

The screenshot shows the A4 Format Software interface. At the top, it displays 'Stand-by' and 'Operator ID: 47 07:40'. Below this are six tabs: 'Inventory', 'Orders', 'Results', 'QC', 'Status', and 'Utility'. The 'Results' tab is currently selected. The interface is divided into several sections:

- Entry fields:** These are fields where data can be entered. Examples include 'Sample ID' (with a cursor), 'Sequence No.' (displaying '200'), 'Disk - Pos.' (displaying '1'), and 'Sample volume' (displaying 'ul').
- Display fields:** These fields show information that cannot be altered. Examples include 'Pre-dil. Off', 'Sample Control Calibrator', 'Position Search', 'Sample Cup Normal', and various test results like 'TSH 0', 'T4 1', 'T3 0', 'HCGSTAT 0', 'CEA 1', 'AFP 1', 'PSA 1', 'FERR 0', 'B12 0', 'P-B12', 'FOL 0', and 'DIG 0'.
- Action buttons:** These include 'Select Control', 'Dilution Factor', 'Register', 'TSH 0', 'T4 1', 'T3 0', 'HCGSTAT 0', 'CEA 1', 'AFP 1', 'PSA 1', 'FERR 0', 'B12 0', 'P-B12', 'FOL 0', 'DIG 0', 'Start', 'Smpl. Stop', 'Stop', 'Alarm', 'Doc', 'Prev', 'Next', 'Undo', and 'Enter'.

Differences between Display and entry fields:

- **Entry fields** are used for entering values and descriptions, e.g. sample IDs. When an entry field is touched it becomes highlighted, the cursor blinks and entries can be made via the keyboard. Entries must always be confirmed by pressing **ENTER**. The entry fields are explained separately in this manual.
- **Display fields** display values or descriptions only. These fields cannot be altered. Display fields are summarized and explained for each screen or window in this manual.

1.3 The Keyboard

The following types of keys are distinguished:

- Action keys
- Navigation keys
- Numeric keys



Action Keys



Activates the STAT mode (for urgent samples).



Starts sample processing.



Interrupts pipetting. Test processing continues for patient samples already pipetted.



Stops the test procedure. All samples still in process must be re-ordered.



Turns the acoustic alarm signal on or off. The alarm message is deleted from the status line.



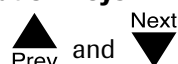
Creates printouts in the form of a list from the displayed screen. For example, work lists can be printed out from the **ORDERS** menu and patient results can be printed out from the **RESULTS** menu. The **DOC** key is not active in every screen. A description of the **DOC** key is given where it is available in those chapters of the manual.

Printing can be interrupted by pressing the **DOC** key a second time. If the Elecsys 2010 is connected to a laboratory network, the **DOC** key can, with appropriate software settings, upload data to the host PC.



The action keys will only be explained in individual chapters of this manual when they are active or when they are of special importance.

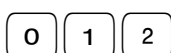
Navigation Keys



Move forwards and backwards. The three basic functions of these two keys depend upon the screen and field in use. They are:

- To scroll up and down in lists (e.g. inventory lists) using **PREV** for up and **NEXT** for down.
- To move between a number of entry fields displayed in a screen.
- To scroll within a field with lists of numbers (e.g. sequence numbers in the **ORDERS** menu) using **PREV** to display the previous number and **NEXT** to display the next number.

Numeric Keys



Keys for entering numeric values.



Deletes data within an entry field. Press **C** if you make a typing error. The character to the left of the cursor will be deleted.

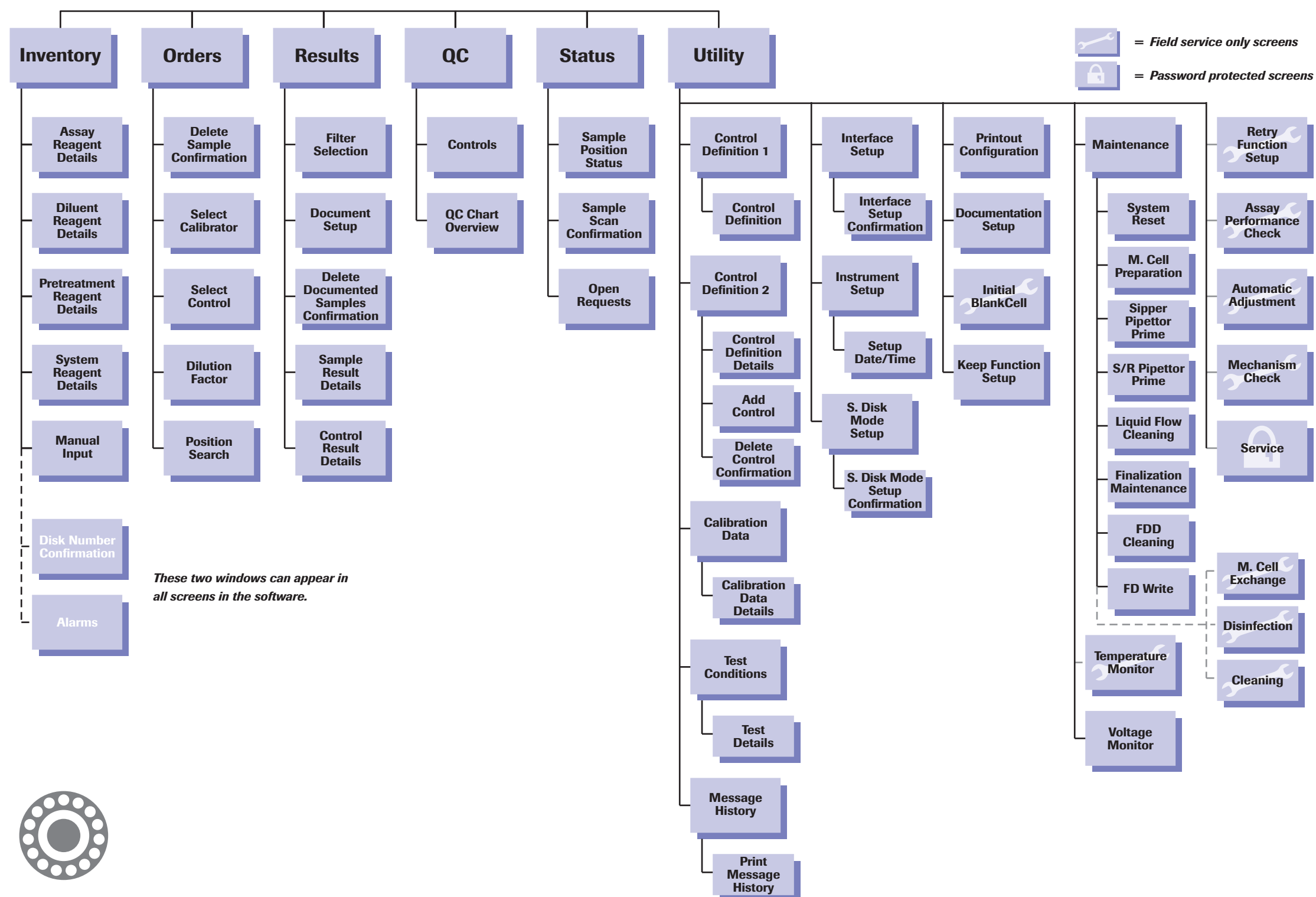


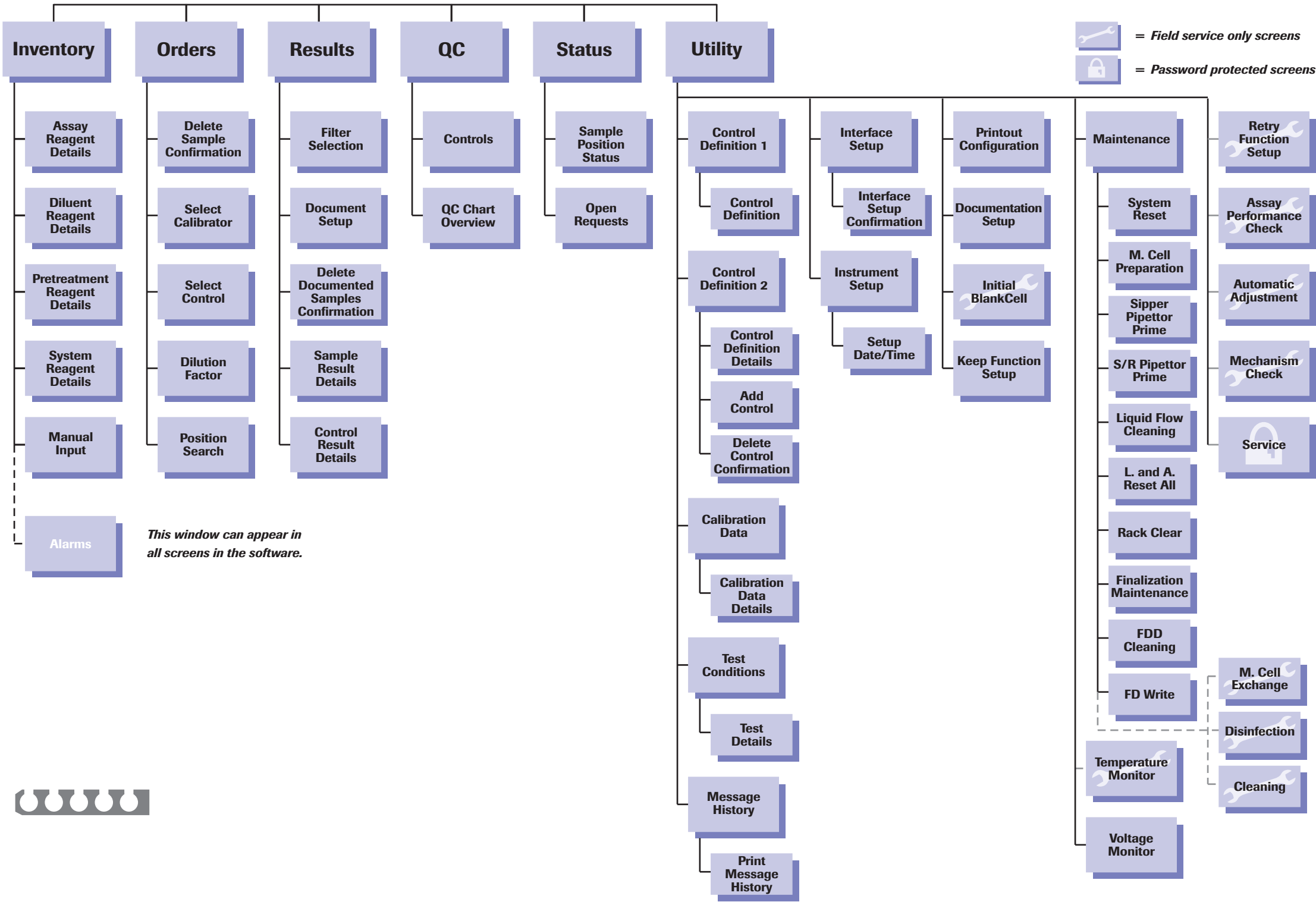
Undoes the last delete procedure made using the **C** key, and restores deleted data.

The ENTER Key

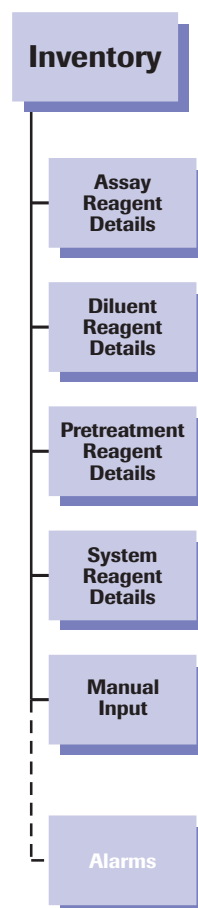
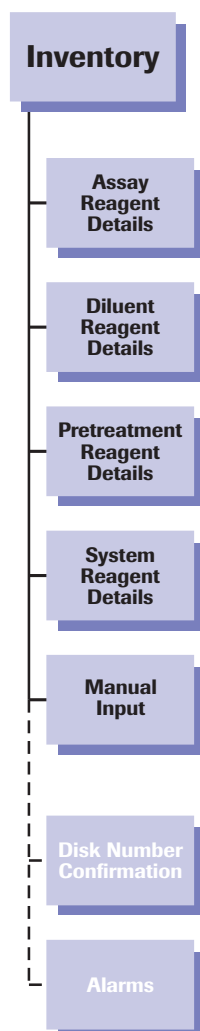


This is one of the most important keys used when operating Elecsys 2010. It **must** be pressed following **each** entry made in an entry field so that the entry can take effect. The **ENTER** key will only then be explained in individual chapters of this manual when the function differs from that described here, or when the result of the function is of particular importance.





2. INVENTORY



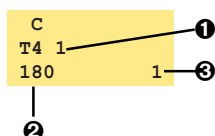
2.1 INVENTORY Screen

Overview of Options

Current information on reagent packs, tips, cups, etc. which are set up on the analyzer is displayed here. Inventory on the analyzer is updated during operation or by a reagent scan. You can load 15 different assays, diluent and/or pretreatment in 18 reagent positions. A maximum of 8 diluent reagent packs can be loaded.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
TSH 0 150 6	C M T4 1 180 1	M T3 0 80 4	RC HCGSTAT 0 100 2	R HCGSTAT 0 100 3	
CEA 1 0 12	AFP 1 70 5	PSA 1 84 13	FERR 0 64 14	FERR 0 94 15	
B12 0 25 7	P-B12 25 8	FOL 0 90 9	DIG 0 18 10	DIG 0 88 11	
		Dil Uni 18 16	Cups 100	Tips 360	
Set 1 Set 2 100% 75%	System Water	Liquid Waste	Solid Waste 507	Reagent Scan	

Screen Buttons



18 test code buttons indicate individual reagent packs on the reagent disk. The middle line on the button represents the test code and generation number (❶). The bottom left number indicates the reagent remaining in the pack in terms of numbers of tests (❷). The bottom right number indicates the reagent's position number on the reagent disk (❸).

The buttons are listed in test number order. Test numbers are encoded in reagent bar codes; however, they can be changed in the **TEST CONDITIONS DETAILS** pop-up window (**UTILITY** folder). Changing the test number allows you to view groups of assays as you desire.



We recommend that you do not change the test number if your analyzer is interfaced to a host. The number utilized by the host interface remains the same as the one encoded in the reagent bar code. This number appears in **INVENTORY** once the software is loaded.

TSH 0		
150		6

A green test button means that a valid calibration exists for the assay. Touch the button to open the **REAGENT DETAILS** pop-up window and gain detailed information about the test. Here a calibration and/or control for this specific reagent pack can be manually requested.

RC		
HCGSTAT 0		
100		2

A yellow test button displaying **RC** and red text means that the system requests an L-Cal for this test. If there is more than one reagent pack of a single lot on the reagent disk, only the reagent pack to be calibrated according to automatic calibration displays **RC**. This calibration can be changed in the assay **REAGENT DETAILS** pop-up window.

R		
HCGSTAT 0		
100		3

A yellow test button displaying an **R** and red text means that a new reagent pack with no L-Cal is available. Another reagent pack for the assay was prioritized by the system for L-Cal, or you have manually deselected the L-Cal (the test button previously displayed **RC**).

M		
T3 0		
80		4

A test button displaying **M** and black text means that a control has been manually requested for this assay in the **REAGENT DETAILS** pop-up window. This function overrides the settings made for this reagent pack in the **CONTROL DEFINITIONS** screen (**UTILITY** folder).

C M		
T4 1		
180		1

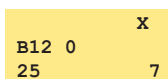
A yellow test button displaying **CM** and black text means that a calibration and a control has been manually requested for this assay in the **REAGENT DETAILS** pop-up window.

C		
T4 1		
180		1

A yellow test button displaying a **C** and black text means that the calibration for the assay was manually requested in **REAGENT DETAILS** or the daily calibration is expired. (Daily calibration applies to qualitative assays only.)

T		
DIG 0		
18		10

A yellow test button displaying a **T** and black text means that the minimum available tests threshold for the assay has been reached. The threshold is defined in the **TEST CONDITIONS DETAILS** pop-up window/**TEST CONDITIONS** screen (**UTILITY** folder).



A yellow test button displaying an **X** and black text means that the reagent pack is expired. Results are flagged with the data alarm 52: Expired reagent pack.



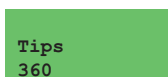
A red test button displaying an **E** and black text means that the reagent pack is empty.



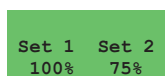
A red test button displaying an **N** and black text means that the test cannot be calibrated; the corresponding pretreatment or diluent reagent pack is missing from the reagent disk.



The number displayed below **Cups**, indicates the remaining number of cups available. The button changes color from green to yellow when the inventory is < 60 (i.e., two trays are empty). The button changes color from yellow to red when the inventory reaches zero.

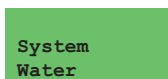


The number displayed below **Tips** indicates the remaining number of disposable tips available. The button changes color from green to yellow when the inventory is < 120 (i.e., two trays are empty). When the inventory reaches zero, the button changes color from yellow to red.

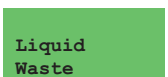


The numbers displayed below **Set 1** and **Set 2** indicate the remaining amounts, in percentages, of the system reagents ProCell and CleanCell for each set. Each set consists of one bottle each of ProCell and CleanCell. The button is green if the percentage of Set 1 and Set 2 is > 30%. The button is yellow if the total of Set 1 and Set 2 is < 30%. The button turns to red if both sets are empty.

Touch this button to open the **SYSTEM REAGENT DETAILS** pop-up window, where you can alter the ProCell lot number. The remaining amounts of ProCell and CleanCell are also displayed.



If this button changes color from green to red, replenish the system water in the container.



If this button changes color from green to red, dispose of the waste in the liquid waste container.

Solid
Waste 507

The number indicates the total number of cups/tips used. If the number exceeds 1100 the button changes color from green to red and the container must be emptied.



Removing the waste container during operation results in an emergency stop (E. Stop).

Should an alarm condition for system water or liquid or solid waste occur during operation, a P. Stop alarm is issued. Tests currently in process are completed. However, if the condition exists when you start operation from Stand-by, a Stop alarm is issued.

Reagent
Scan

Initiates a scan of the reagent pack bar code labels on the reagent disk. In addition, the gripper checks the loading of assay cups and tips, and the sipper probe checks the levels of ProCell and CleanCell. The word Scanning flashes on the status line while the scan is active. When the scan is complete, the **INVENTORY** screen updates all the test buttons, cups, tips and ProCell/CleanCell. A reagent scan can only be initiated from Stand-by mode.



Ensure all ProCell and CleanCell lids are open when you initiate a reagent scan.

Print



Prints out an inventory report.

2.2 REAGENT DETAILS Pop-up Window

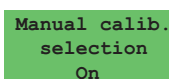
Detailed information on the assay's reagent pack is displayed here. It is opened by touching a test button in the **INVENTORY** screen.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
TSH 0 150 6	Reagent Details T4 1 Pos.: 1 No. of tests available : 180 Last lot cal. date (L-Cal) : 03/16/2001 recommended at : 04/15/2001 Last rg. pk cal date (R-Cal) : 03/16/2001 recommended at : 03/23/2001 Assay lot no. : 194389 Reagent pack number : 2873 Lot exp. date : 10/2001 First registration : 03/16/2001 08:44				R HCGSTAT 0 100 3
CEA 1 E 0 12					FERR 0 94 15
B12 0 X 25 7					DIG 0 88 11
	Manual calib. selection On Manual control selection On Close				Tips 360
Set 1 Set 2 100% 75%	Water	Waste	Waste 507	Reagent Scan	

Display Fields

Test details appear in the following fields: The test name and generation in Reagent details and its position (**Pos.**) on the disk, the remaining **Number of tests available**, the date of the last lot (**Last lot cal. date, L-Cal**) and reagent pack calibrations (**Last rg. Pk cal. date, R-Cal**) and the recommended at date for the next calibration. Furthermore, **Assay lot no.**, the **Reagent pack number**, the **Lot exp. date** (expiration) and the **First registration** date when the reagent pack was scanned-in for the first time are displayed.

Screen Buttons

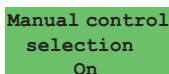
A green rectangular button with the text "Manual calib. selection" on the top line and "On" on the bottom line.

Manually requests (**On**) or deselects (**Off**) a calibration for the displayed test's reagent pack. When the **REAGENT DETAILS** pop-up window is closed, the yellow test screen button displays a **C** and black text. Should more than one reagent pack from the same lot be on the reagent disk and the button is toggled to **On**, only the selected reagent pack will be calibrated.



Automatic calibration: 1. The analyzer automatically calibrates every reagent pack when a calibrator for this test is loaded on the instrument. 2. Should two reagent packs from the same lot be on the reagent disk, the analyzer automatically calibrates that was scanned last.

The automatic calibration can be overridden by manually requesting a calibration (**Manual calib. selection On**).

A green rectangular button with the text "Manual control selection" on the top line and "On" on the bottom line.

Manually requests (**On**) or deselects (**Off**) a control for the displayed test. If **On** is selected then the control settings, set in **CONTROL DEFINITIONS** screen (**UTILITY** folder), no longer apply. When the **REAGENT DETAILS** pop-up window is closed, the green test button displays an **M** and black text.

Should more than one reagent pack of the same test be on the reagent disk and the button is toggled to **On**, the control will only be measured with the selected reagent pack.

2.3 REAGENT DETAILS Pop-up Windows for Diluent and Pretreatment

These two windows are opened by touching the corresponding diluent or pretreatment button in the **INVENTORY** folder. These windows differ in content in some aspect only (see below).

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
TSH 0 150 6	Reagent Details Dil Uni Pos.: 16				R HCGSTAT 0 100 3
CEA 1 E 0 12	No. of milliliters available : 18				FERR 0 94 15
B12 0 X 25 7	Diluent lot no. : 194408 Reagent pack number : 4706 Lot exp. date : 07/2001 First registration : 03/16/2001 08:44				DIG 0 88 11
	Close				Tips 360
Set 1 Set 2 100% 75%	Water	Waste	Waste	507	Reagent Scan

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
TSH 0 150 6	Reagent Details P-B12 Pos.: 8				R HCGSTAT 0 100 3
CEA 1 E 0 12	No. of tests available : 25				FERR 0 94 15
B12 0 X 25 7	Pretreatment lot no. : 674804 Reagent pack number : 91 First registration : 03/16/2001 08:44				DIG 0 88 11
	Close				Tips 360
Set 1 Set 2 100% 75%	Water	Waste	Waste	507	Reagent Scan

Display Fields

The following information for the selected diluent or pretreatment is displayed: Name (**Reagent Details**) and position (**Pos.**) on the reagent disk, **Diluent lot no.** or **Pretreatment lot no.** and Reagent pack number as well as the **First registration** date when the reagent pack was scanned-in for the first time.

- The actual amount of diluent is given in milliliters (**No. of milliliters available**).
- The actual amount of pretreatment is given in terms of number of tests (**No. of tests available**).

2.4 SYSTEM REAGENT DETAILS Pop-up Window

Open this window by touching the test button for system reagents (**Set 1** and **Set 2** for ProCell and CleanCell).

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
TSH 0 150 6	C T4 18	System Reagent Details Set 1 Set 2 PC CC PC CC 100% 100% 75% 78% Lot No. of PC Lot No. of PC 67400701 67400701 <div>OK</div> <div>Cancel</div>		2	R HCGSTAT 0 100 3
CEA 1 0 12	E AF 70			14	FERR 0 94 15
B12 0 25 7	X P- 25			T 10	DIG 0 88 11
					Tips 360
Set 1 Set 2 100% 75%	System Water	Liquid Waste	Solid Waste	507	Reagent Scan

Display and Entry Fields

The amount of fluid in the bottles for set 1 and set 2 are displayed in percentages.

Lot No. of PC

Display and entry field for the lot number for ProCell for each set.

2.5 MANUAL INPUT Pop-up Window

Should the bar code reader be unable to read a reagent pack bar code label, you can enter the reagent bar code number manually. To do so touch a blank test button on the **INVENTORY** screen. When the appropriate information is entered and confirmed, the reagent pack information appears on the previously blank button you selected.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
TSH 0 150 6	C M T4 1 180 1	M T3 0	RC HCGSTAT 0	R HCGSTAT 0 100 3	
CEA 1 E 0 12	AFP 1 70 5	Manual Input Pos.: 17 Rgt. BC no. : 0000184689782464 Lot no. : 193398 Test code : TNTSTAT OK Cancel		FERR 0 94 15	
B12 0 X 25 7	P-B12 X 25 8			DIG 0 88 11	
				Tips 360	
Set 1 Set 2 100% 75%	System Water	Liquid Waste	Solid Waste 507	Reagent Scan	



Reagent pack bar codes can only be manually entered if the lot number has previously been used on the analyzer. If the bar code of a new reagent pack cannot be read, place another reagent pack onto the reagent disk and manually enter the bar code number of the unreadable bar code label at a later date.

If you enter a **bottle number** and its lot number has not been successfully scanned before, the **OK** and **Cancel** buttons are not active.

Please note: The reagent pack must be placed onto the correct position on the reagent disk; the position must correspond to the position displayed on the selected button.

A manually entered reagent pack can be overwritten by placing another reagent pack in the same position as that of the manually entered reagent pack and performing a reagent scan.

Display and Entry Fields


Details of manually entered reagent packs are displayed in the following fields: The position on the disk (**Pos.**), **Lot no.** and **Test code**. They are displayed automatically following entry and confirmation of the bar code number.

Rgt. BC no.

Display and entry of the 15-digit bar code on the reagent pack label. After confirming the 15-digit bar code number, the software adds a leading zero to the number.

2.6 DISK NUMBER CONFIRMATION Pop-up Window



If you are using more than one disk on the Elecsys 2010 disk system, the **DISK NUMBER CONFIRMATION** pop-up window appears when you touch the  button. This is independent of which screen is displayed at the time of initiating the start. You will be requested to confirm the number of the disk on the analyzer.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
TSH 0 150 6	C M T4 1 180	Confirmation Current disk no. = 0 Resume this operation? <div>Resume Cancel</div>		2	R HCGSTAT 0 100 3
CEA 1 0 12	AFP 1 70			14	FERR 0 94 15
B12 0 25 7	P-B12 25			T 10	DIG 0 88 11
		Dil Uni 18 16	Cups 100	Tips 360	
Set 1 Set 2 100% 75%	System Water	Liquid Waste	Solid Waste 507	Reagent Scan	

Display Fields

Displays the number of the sample disk currently loaded on the analyzer.



The sample disks are not physically numbered or coded. The disk number in use must be tracked by the operator.

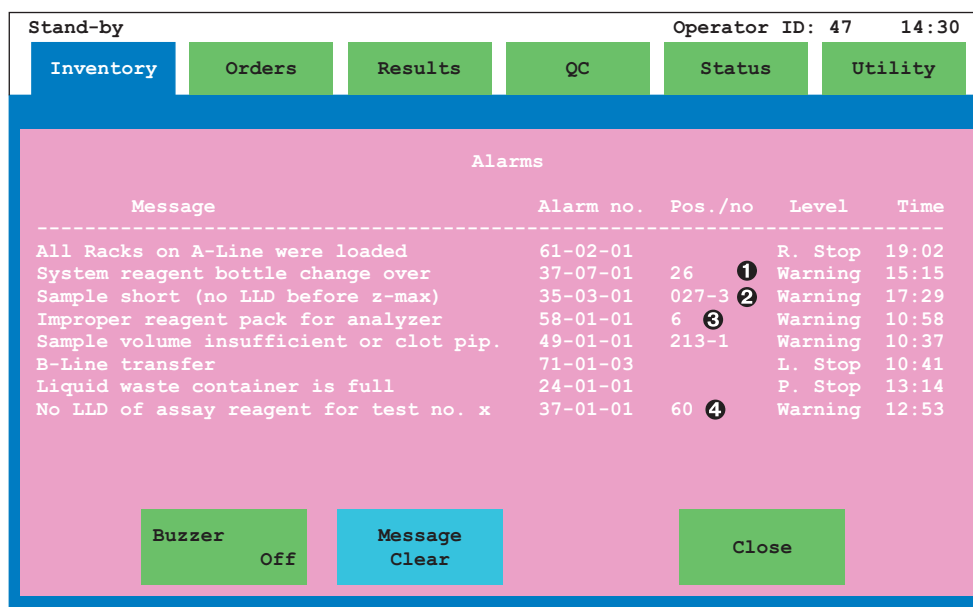
Screen Buttons



This button enables you to resume operation with the indicated sample disk.

2.7 ALARM Pop-up Window

When an alarm occurs, it is displayed on the status line. Additional alarms which may occur at the same time must be viewed in the **ALARM** pop-up window. This displays the last 10 alarm messages in chronological order, and can be opened by pressing **ALARM**. Although you can delete these messages from the window, they are still available in **MESSAGE HISTORY** screen (**UTILITY** folder), where they can be printed out.



Display Fields

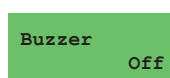
Display the alarm message, alarm code, position number, level and time of occurrence of the alarm.

Depending on the type of alarm and the affected component, the alarm screen indicates, amongst other things, the position number of the reagent pack on the reagent disk, the position of the rack (if a rack system is used), the sequence number or the number of the test. The example screen above displays some alarm messages. For detailed information about alarm messages, see the appropriate chapter in the User's Guide.

Legend:

- ❶ = Sequence number
- ❷ = Rack position number
- ❸ = Reagent pack position number on the reagent disk
- ❹ = Test number

Screen Buttons

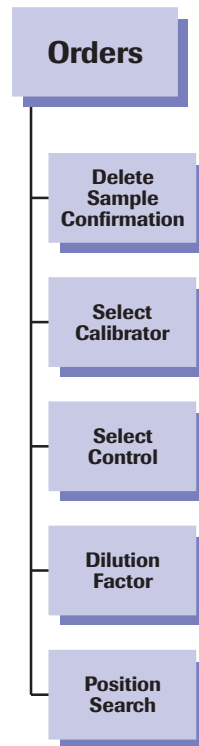


Switches the audible alarm on or off.



Clears all selected messages on the **ALARM** pop-up window.

3. ORDERS



3.1 ORDERS Screen

Overview of Options

In the **ORDERS** screen you can request, check, alter or delete existing orders. You can search for specific samples using the sample ID or sequence number, select dilution factors for diluted samples and print out a work list. Furthermore, you can manually order samples, calibrators and controls. STAT sample orders can be recognized by **STAT** (shown in red in the status line) and **STAT sample** instead of **Sample ID**.



Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
Sample ID :	<input type="text"/>	Pre-dil. Off		Sample Control	
Sequence No. :	200	Select Control	Dilution Factor	Calibrator	
Disk - Pos. :	1 -	Position Search	Sample Cup Normal	Register	
Sample volume :	ul				
TSH 0	T4 1	T3 0	HCGSTAT 0	CEA 1	
AFP 1	PSA 1	FERR 0	B12 0	P-B12	
FOL 0	DIG 0				



Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
Sample ID :	<input type="text"/>	Pre-dil. Off		Sample Control	
Sequence No. :	200	Select Control	Dilution Factor	Calibrator	
Rack ID - Pos. :	-	Position Search	Sample Cup Normal	Register	
Sample volume :	ul				
TSH 0	T4 1	T3 0	HCGSTAT 0	CEA 1	
AFP 1	PSA 1	FERR 0	B12 0	P-B12	
FOL 0	DIG 0				

Display and Entry Fields

The sample volume for the selected test (without dead volume) is displayed in the **Sample volume** field.

Sample ID

Display or entry of sample ID. A sample ID of up to 22 numeric characters can be entered in this field. Sample IDs can also comprise alphanumeric characters when downloaded from the host. A number preceded by an @ means the ordered sample has no ID or the bar code was not read.



The field name changes according to the type of sample selected: **Control ID**, **Calibrator ID**, **STAT Sample ID** or **STAT Control ID**.



The field name changes according to the type of sample selected: **Control ID** or **Calibrator ID**



You can find detailed information about STAT samples in the Tutorial Guide.

Should no sample ID have been assigned to an order, then the sequence number is displayed preceded by an @ as the default sample ID.

Sequence Number

Display or entry of the processing number of the ordered sample. The next available sequence number (1 to 9999) is assigned automatically.

A number can only then be re-assigned when it is no longer linked to a result or ID. This link is deleted in the **RESULTS** screen.

To search for samples, type in the required number or use the **NEXT** or **PREV** keys respectively, when the cursor is on the sequence number.

When the sequence number reaches 9999, then the next order number is 1 should this be free and all other numbers have been used. The **Register** button does not advance the sequence number from 9999 to 1 or vice versa.



Disk - Pos.

The position number consists of two fields. The first is the sample disk number (0 to 9) and the second is the sample disk position (1 to 30). Entries in both fields can be altered. The next sample disk position is displayed after an entry is made and the **Register** button is touched. If the position number 30 has been reached then the next position number for a new order is 1.



Rack-ID - Pos.

This position number consists of two fields. The first is the rack ID number, the second is the rack position number (1 to 5). Entries in both fields can be altered. The next position on the rack is displayed after an entry is made and the **Register** button is touched. If the position number 5 has been reached then the next position number is 1.

Screen Buttons

Test Buttons

A maximum of 15 tests are available. All tests loaded onto the disk are available for selection. The test button changes color from green to light blue following the selection of a test.

Pre-dil. Off

On is for a manually pre-diluted sample. The letter **P** (predilution) behind the sequence number in the results printout and in the **RESULTS** screen indicates that the sample has still to be calculated.

Sample
Control
Calibrator

Display or selection of the desired sample type. The default setting is **Sample**.

Select
Control

Opens the pop-up window for selecting controls. This option is used for non-bar coded controls such as pre-defined non-Roche controls or Roche controls with missing or damaged bar codes.

Dilution
Factor

Touch a test button for a sample requiring dilution, then touch the **Dilution factor** button to open the **DILUTION FACTOR** pop-up window. If a dilution factor is selected in this window, the sample is automatically diluted prior to analysis. The available dilution factors are set by the software.

The function is not available if the text on the button is white. The assay cannot be diluted or there is no diluent on the analyzer.

Position
Search

Opens the **POSITION SEARCH** pop-up window and allows you to search for a specific sample by means of either disk or position number provided that the sample has not been started.

Sample Cup
Normal

Offers the choice between normal or reduced sample volumes. The last option reduces the dead volume when using sample cups directly on the sample disk or rack, or on top of a primary sample tube. The default setting is **Normal**. The default for this feature is set in the **KEEP FUNCTION SETUP** screen. Refer to Chapter 2, System Description, in the Reference Guide, for a table of reduced dead volumes.

Register

Registers and confirms your sample orders. If an order has already been registered, the button color changes from yellow to green.



You must confirm every alteration to a registered sample order by touching the **Register** button, even if the button color is green.

Print



Prints out a work list of the current sample disk or all programmed/downloaded sample orders in the rack system. Additionally, for disk analyzers only, all required inventory information is included in the work list.

STAT Orders



Orders urgent samples, controls or calibrators (STAT). The word STAT appears in red in the status line. Please refer to the Tutorial Guide for more detailed information about STAT samples.



The field **Sample ID** changes to **STAT Sample ID**, **Control ID** to **STAT Control ID**, and **Calibrator ID** changes to **STAT Calibrator ID**.

Special Key Functions



In addition to the basic functions (deleting characters within an entry field), it is possible to delete a complete sample order using the **C** key. To do so the cursor must be in either a **Sequence Number** or **Sample ID** field of a previously ordered sample that has been confirmed by touching **Register** or downloaded from the host. After pressing the **C** key the **DELETE SAMPLE CONFIRMATION** pop-up window appears.

3.2 DELETE SAMPLE CONFIRMATION Pop-up Window

This pop-up window is opened by pressing the **C** key when the cursor is in either a **Sequence Number** or **Sample ID** field. From here you can either delete a sample record from the system by touching the **OK** button or cancel the delete procedure by touching the **Cancel** button.

Stand-by Operator ID: 47 07:40

Inventory Orders Results QC Status Utility

Sample ID : 12345 Pre-dil. Off Sample Control Calibrator

Sequence No. : 200 Select Control Dilution Factor

Disk - Pos. : 1 - 7 Register

Sample volume : 45 ul

Confirmation

Delete this sample record?

OK Cancel

TSH 0 T4 1

AFP 1 PSA 1

FOL 0 DIG 0

CEA 1

P-B12

3.3 SELECT CALIBRATOR Pop-up Window

Here you can manually assign calibrators, for example if the bar code is defective or when a vial other than a CalSet vial is to be used. The vial is designated as a Roche Vial after the manual selection of the calibrator, and cannot be altered. This is a useful window if you pour your calibrators into a container other than a CalSet vial.

Refer to Chapter 3 in the Tutorial Guide.

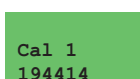
Display and Entry Fields

The selected assay is displayed in the **Calibrator test code** field.

Pos.

Display or entry of the position number of the reagent pack on the reagent disk.

Screen Buttons

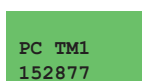


Display and select the calibrators 1 and 2. Touch the appropriate calibrator button to select it. Once selected the button changes color from green to light blue.

3.4 SELECT CONTROL Pop-up Window

Here you can manually assign controls, for example pre-defined non-Roche controls, or for Roche controls with defective or missing bar codes. For further details please refer to Chapter 2 in the Tutorial Guide.

Screen Buttons



Touch the button to select the required control. Once selected, the button changes color from green to light blue.

3.5 DILUTION FACTOR Pop-up Window

Here you can select a dilution factor, which is then displayed in the test button. Refer to the package insert for recommended dilution factors.

HGSTAT
Dil.= 100

This window is available only for assays encoded in the diluent bar code as being able to be diluted and when diluent is on the analyzer.

Stand-by Operator ID: 47 07:40

Inventory Orders Results QC Status Utility

Sample ID : Pre-dil. Off Sample

Sequence No. : 200 Select Dilution Control

Disk - Pos. Register

Sample vol

	Dilution Factor		HCGSTAT
TSH 0	2	5	No dilution
AFP 1	10	20	
FOL 0	50	100	Close

CEA 1

P-B12



If a dilution factor has been set in **TEST CONDITIONS** in the **UTILITY** folder, then the corresponding assay will be diluted by this factor when selected for all patients samples for which this assay was ordered.

Screen Buttons

2

There are six dilution selection buttons available and a button to select no dilution. Once selected, the dilution button changes color from green to light blue.

Depending upon which dilution factor is selected, different volumes of sample and diluent are aspirated to complete the dilution. Some dilutions are completed in two steps. See the following table.

Dilution Ratio	First Dilution		Second Dilution	
	Sample	Diluent	Diluted Sample	Diluent
1:2	50 µL	50 µL	–	–
1:5	40 µL	160 µL	–	–
1:10	20 µL	180 µL	–	–
1:20	20 µL	180 µL	100 µL	100 µL
1:50	20 µL	180 µL	40 µL	160 µL
1:100	20 µL	180 µL	20 µL	180 µL

3.6 POSITION SEARCH Pop-up Window

Here you can search for a sample, by disk number and position or by rack ID and position, provided the sample has not been completed.

Stand-by

Operator ID: 4707:40

Inventory

Orders

Results

QC

Status

Utility

Sample ID :

Pre-dil. Off

Sample Control

Sequence No. : 200

Select Control

Dilution Factor

Disk - Pos. : 1 -

Register

Sample volume : u1

Position Search

TSH 0

T4 1

Disk no. :

Position no. :

Search

Close

CEA 1

AFP 1

PSA 1

P-B12

FOL 0

DIG 0

Entry Fields



Disk no.
There are 10 disk numbers (0 - 9) available.



Rack ID
Leading zeros are added by the system to a manual rack ID entry.

Position no.
The numbers 1-30 are possible on a disk system and 1-5 on a rack system.



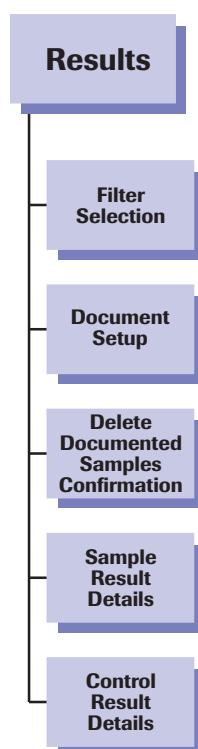
If using a rack system the position search function is only available after a batch has been downloaded from the host.

Screen Buttons



Initiates a search for the desired sample. The window closes and returns to the **ORDERS** screen. The desired sample is displayed on the screen.

4. RESULTS



4.1 RESULTS Screen

Overview of Options

This screen displays the results of a maximum of 600 samples and tests. Results are overwritten on a first in, first out basis (FIFO). All samples can be displayed, printed out or transmitted to the host. You can search for results in this screen by entering the sample ID or sequence number. You can manually delete documented samples from the database. The filter function allows a selective display of the results.



Stand-by		Operator ID: 47		15:00	
Inventory	Orders	Results	QC	Status	Utility
Sample ID	:	23456	P	Filter	Document
Sequence No.	:	1		Off	
Disk - Pos.	:	1 - 7		Samples : 101	Delete Doc. Samples
14:46 HCGSTAT 0 189					



Stand-by		Operator ID: 47		15:00	
Inventory	Orders	Results	QC	Status	Utility
Sample ID	:	23456	P	Filter	Document
Sequence No.	:	1	Documented	Off	
Rack ID - Pos.	:	0005 - 3		Samples : 101	Delete Doc. Samples
14:46 HCGSTAT 0 189					

Display and Entry Fields

Sample ID

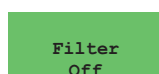
Display and entry of the sample ID. You can scroll for samples or controls using the **NEXT** or **PREV** keys. Samples designated as manually pre-diluted appear with a **P** next to the **Sample ID** field.

Sequence No.

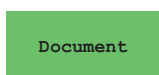
Display and entry of the sequence number. You can scroll for a specific sequence number using the **NEXT** or **PREV** keys. The word **Documented** displayed next to the **Sequence No.** field means that the sample has been documented. Document options are set in the **DOCUMENTATION SETUP** screen in **UTILITY**.

The following sample information is also displayed:

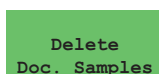
The position number of the selected sample on the disk (**Disk – Pos.**) or rack (**Rack ID – Pos.**). The number of samples displayed in the **Samples** field is determined by the setting in the **FILTER SELECTION** pop-up window.

Screen Buttons

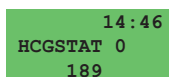
Opens the **FILTER SELECTION** pop-up window, where you can choose between different results filters.



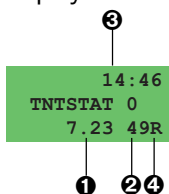
Opens the **DOCUMENT SETUP** pop-up window. Here you can document a number of samples according to their sequence number.



Touch this button to open the **DELETE DOCUMENTED SAMPLES CONFIRMATION** pop-up window, where it is possible to delete several samples at a time (selection via sequence number).



A maximum of 15 test results are displayed for a sample. Data is displayed on the buttons in real time. By touching a test button you can open the corresponding **RESULT DETAILS** pop-up window. The data displayed on a test button can include the following:



- ❶ Test result.
- ❷ Data alarm. Should more than one data alarm for a result occur, then only the alarm with the highest priority appears. For further details please refer to Chapter 2, Data Alarms in the User's Guide.
- ❸ Time the result is available
- ❹ S = blocked by the system, B = blocked by the operator, R = released by the operator.

Print

Depending on the document options selected in the **DOCUMENTATION SETUP** screen (**UTILITY** folder), you can print or transmit a report to the host, or both, for the sample ID displayed.

4.2 FILTER SELECTION Pop-up Window

This pop-up window is opened by touching the **Filter** button. Here you can choose to filter the type of samples you want to view, document or print. The choices made directly influence the number of samples displayed in the **Samples** field (**RESULTS** screen).

Display and Entry Fields

The filters offer the following options:

The **Routine/STAT** fields allow you to filter the samples **Routine** (routine samples only), **STAT** (urgent samples only) or **All** (all samples). In the **Type** fields you can filter the sample type **Samples** (patient samples only), **Controls** (controls only) or **All** (all sample types). In the **Document** fields you can select the documentation selection filters: **Non Doc.** (non-documented results), **Doc.** (documented results) or **All** (all results). The buttons change color from green to light blue on selection.

Example: When **STAT**, **Controls** and **Doc.** are selected, only the documented control results will be displayed as urgent.

Screen Buttons



Activates or deactivates filtering.

4.3 DOCUMENT SETUP Pop-up Window

This pop-up window is opened by touching the **Document** button. Here you can select and documented a range of samples by sequence number. The samples can be printed as needed and/or uploaded to the host. The type of documentation depends on the settings made in the **DOCUMENTATION** screen (**UTILITY** folder).

Stand-by Operator ID: 47 15:00

Inventory Orders Results QC Status Utility

Sample ID : 23456 P

Sequence No. : 1 Documented

Disk - Pos. : 1 - 7

Samples : 101

Filter Off

Document

Delete Doc. Samples

Print/Upload

First Seq. No. : 1

Last Seq. No. : 9999

OK Cancel

14:46
HCGSTAT 0
189

Entry Fields

First Seq. No.

Enter the first sequence number (1-9999) of the range of samples to document.

Last Seq. No.

Enter the last sequence number (1-9999) of the range of samples to document.

4.4 DELETE DOCUMENT SAMPLES CONFIRMATION Pop-up Window

Touch **Delete Doc. Samples** to open this pop-up window. Here you can confirm the deletion of all documented samples. Deleting all documented samples in the system increases the space in the database and frees the corresponding sequence numbers.

Stand-by Operator ID: 47 15:00

Inventory Orders Results QC Status Utility

Sample ID : 23456 P

Sequence No. : 1 Documented

Disk - Pos. : 1 - 7

Samples : 101

14:46 HCGSTAT 0 189

Confirmation

Delete all documented samples?

OK Cancel

Filter Off Document Delete Doc. Samples

4.5 RESULT DETAILS Pop-up Window for a Sample

You can display the details of test results by touching the appropriate test button. Only results that have not been documented can be blocked or released.



It is only possible to block or release results manually if automatic documentation is set to OFF in the **DOCUMENTATION SETUP** screen (**UTILITY** folder).

Stand-by Operator ID: 47 15:00

Inventory Orders Results QC Status Utility

Sample ID : 76354446

Sequence No. : 154 Do

Disk - Pos. : 1 - 7

14:16 TNTSTAT 7.23 49

14:25 TSH 0 2.10

TSH 0

Sampling time: 14:07

Ready time : 14:25

Result : 2.10 uIU/ml

Lower limit : 0.27

Upper limit : 4.2

Note :

Dil. factor :

Flags :

Status : Released

Signal :

Block Close

Document Delete Doc. Samples

Display Fields

The following information is displayed:

The test code, sampling time, ready time, and the result with corresponding units. The upper and lower limits of the expected values for the test are displayed in the **Lower limit** and **Upper limit** fields; both these values can be altered in the **TEST CONDITIONS DETAILS** pop-up window.

Further information on results appear in the **Note** field; the dilution factor, if used, flags and status of the results are also given where appropriate. A signal generated by the assay result appears if the effective signal has been set by technical support.

4.6 RESULT DETAILS Pop-up Window for a Control

You can open this window by touching a test button when a control is displayed in the **RESULTS** screen. The detailed control results of the selected test are displayed.



It is only possible to block or release results manually if automatic documentation is set to OFF in the **DOCUMENTATION SETUP** screen (**UTILITY** folder).

Stand-by		Operator ID: 47		15:00	
Inventory	Orders	Results	QC	Status	Utility
Control ID : PC TM1				Document	
Sequence No. : 15		Do			
Disk - Pos. : 1 - 21					
CEA 1 14:30 4.81	PSA 1 14:30 11.63	CEA 1 Sampling time: 14:11 Ready time : 14:30 Result : 4.81 ng/ml Target value : 3.50 Lower, upper : 4.60 Note : 3.50 - 5.36 Dil. factor : Flags : Status : Released Signal :		Delete oc. Samples	
		Block		Close	

Display Fields

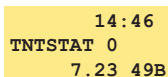
With two exceptions, the information fields are the same as those described in the RESULTS DETAILS Pop-up window for a Sample, Chapter 4.5.

The control target value as well as the lower/upper limits are displayed. They are encoded in the control bar code card or reagent pack bar code (Roche controls). Data for non-Roche controls is entered in the **CONTROL DEFINITION DETAILS** pop-up window, **CONTROL DEFINITION** screen (**UTILITY** folder). The target value and the control range appear on report printouts.

Screen Buttons



This button toggles between **Block** (the default setting) and **Release**. After touching the button displaying **Block**, the display changes to **Release**. After closing and reopening the window the **Status** field displays **Blocked**.

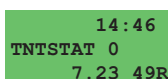


```
14:46
TNTSTAT 0
7.23 49B
```

The color of the corresponding test button in the **RESULTS** screen changes to yellow and displays the letter **B**.



"**R**" and "**B**" are printed in **Single** and **Multiple** modes only. They cannot be printed in the **Condensed** mode. For further information about the print modes, refer to chapter 7.10, PRINTOUT CONFIGURATION Screen.

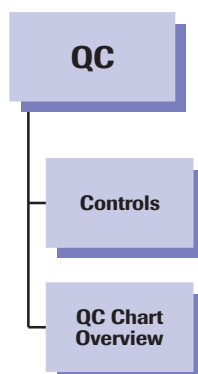


```
14:46
TNTSTAT 0
7.23 49R
```

Blocked results are printed with the status **B** and/or uploaded to the host. If a result is manually released, the color of the corresponding test button in the **RESULTS** screen changes to green and displays the letter **R**. Released results are printed and/or uploaded to the host with the status **R**.

"No value" appears for results blocked by the system.

5. QC



5.1 QC Screen (Quality Control)

Overview of Options

The QC screen displays the distribution of the measured results around the target value of a quality control test for the test lot/control lot combination. A maximum of 60 control charts are available to be displayed. As soon as the 51st chart is stored the oldest chart entry is tagged with the message "This data will be deleted!" in red characters. This is repeated until the 60th chart is generated. As soon as the 61st chart is generated, the system deletes the first chart tagged. Charts can also be deleted manually by the user, refer to chapter 5.3, QC CHART OVERVIEW Pop-up Window.

You can block control results when the selected result is highlighted.

Stand-by				Operator ID: 47 07:40	
Inventory	Orders	Results	QC	Status	Utility
HCGSTAT 0 mIU/ml Reagent lot no. : 193367 Last L-Cal date : 03/16/2001 This data will be deleted!		Test no. : 170 Control ID : PCU1 Control lot : 192093		No. of Charts : 2 Controls Overview	
n=5 mean= 7.98 SD= 0.227 CV = 2.84 median= 8.01 min= 7.59 max= 8.16		5.73 8.13 10.63			
03/25/2001 09:49 8.00 03/23/2001 09:05 8.12 03/20/2001 08:58 8.01 03/16/2001 11:50 8.16 03/16/2001 10:36 8.59 03/16/2001 08:05 No Value 255		x x x x x x		 	
		B		Line up ----- Page 1/1 ----- Line down	

Display and Entry Fields

Test code

The number of the displayed test.

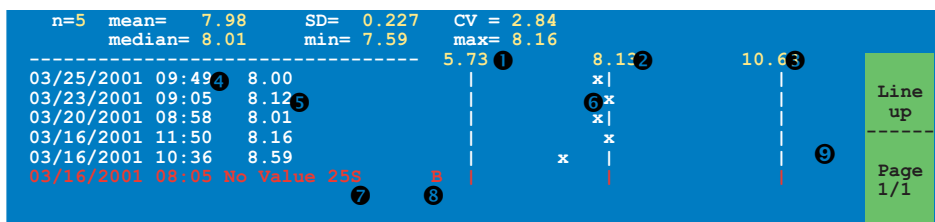
- Test and control-specific information:

Name and unit for the selected test. Reagent lot number and control lot, the control name (**Control ID**) as well as the date of the last lot calibration (**Last L-Cal**) or last reagent calibration (**Last R-Cal date**). **No. of Charts** displays the number of all results charts stored and the message "This data will be deleted".

- Results-specific details:

Number of control results for the chart (**n**), mean and median, standard deviation (**SD**) and the coefficient of variation (**cv**). **cv** will only be calculated if a minimum of five results is available. Further, the **min** and **max** fields display the minimum and maximum control results of all results on the chart.

- The results values in detail:



- ❶ The lower limit of the control range.
- ❷ The target value of the control.
- ❸ The upper limit of the control range.
- ❹ The date and time the control result was measured.
- ❺ The control result.
- ❻ The control result displayed graphically as an **x**.
- ❼ Data flags that occurred for the control result.
- ❽ If a control result is blocked, a **B** appears here.
- ❾ **Page 1/x**: A maximum of five pages with a total of 60 individual results can be displayed (13 results per screen).

Screen Buttons



Opens the window where you can select up to a maximum of 15 controls.



Opens the **CHART OVERVIEW** pop-up window. Displays which controls are measured with the test selected in the **QC** screen.

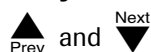


Scrolls up within a list of results after having selected a result from the list.



Scrolls down within a list of results after having selected a result from the list.

Special Keyboard Functions



- Scrolls from one list to another if more than 13 control results exist for the test.
- If the cursor is in the **Test no.** field, **NEXT** displays the next test number and **PREV** displays the previous test number.



Blocks a result when a selected control result is highlighted. Pressing this key again releases the result and returns the text to its previous state and recalculates the statistics.

Print



Prints a QC report for the control displayed.

5.2 CONTROLS Pop-up Window

Touch the **Controls** button to open this window and select a control.

Stand-by

Operator ID: 47

07:40

Inventory

Orders

Results

QC

Status

Utility

TSH 0

uIU/ml

Test No. : 10

No. of

PC TM1
152877

PC TM2
152878

PC CARD1
156415

PC CARD2
156416

PC U1
153688

PC U2
153692

PC TSH
153511

OK

Cancel

Screen Buttons

A maximum of 15 control buttons are displayed. You can open the **QC CHART OVERVIEW** pop-up window by touching one of these buttons to select the results of the chosen control.

5.3 QC CHART OVERVIEW Pop-up window

This pop-up window is opened by touching the Overview button in the **QC** screen or by selecting a control in the **CONTROLS** pop-up window. Here you can select a test lot/control lot combination to display the individual control results in the **QC** screen.

Stand-by

Operator ID: 47

07:40

Inventory

Orders

Results

QC

Status

Utility

QC Chart Overview Test - Controls

TestCode	Lot no.	Cont.ID	Lot no.	Last Entry
TSH 0	198951	PCU1	153688	09/09/2001 15:59
TSH 0	198951	PCU1	153690	10/09/2001 13:02
TSH 0	198951	PCU2	153692	13/09/2001 14:55
TSH 0	198951	PCU2	153694	13/09/2001 09:22
TSH 0	198951	PC-THS	153511	13/09/2001 07:10
TSH 0	198951	PCU1	153696	14/09/2001 18:55
TSH 0	198951	CONTROL G	197600	15/09/2001 21:13
TSH 0	198951	CONTROL H	197604	16/09/2001 14:35
TSH 0	198951	CONTROL I	197608	21/09/2001 17:53
TSH 0	198951	CONTROL J	197612	23/09/2001 11:13

UP

Page 1/2

DOWN

Open Chart

Delete Chart

Close

Display and Entry Fields

The test code is displayed in the **TestCode** column. The control measured by the test is displayed in the **Cont. ID** column. The date and time the measurement was made is displayed in the **Last Entry** column. To select a test lot/control lot combination, touch the appropriate line.

Screen Buttons

Open Chart

Opens the **QC** screen with the results chart for the selected test lot/control lot combination.

Delete Chart

Deletes the results chart for the selected test lot/control lot combination.

UP

Scrolls upwards within a page of test lot/control lot combinations. To activate this function you must first select a combination from the list.



If more than 13 test lot/control lot combinations are listed, you can use the **PREV** key to view the previous page and the **NEXT** key to view the next page of test/control combinations.

DOWN

Scrolls downwards within a page of test/control combinations. To activate this function you must first select a combination from the list.

Different Layouts of the QC CHART OVERVIEW pop-up window

If you open the window via the **OVERVIEW** field in the **QC** screen, it has the following appearance:

The test code is displayed in the first column on the left. All the controls that were measured with this test are displayed in the third column under **Cont. ID**.

Stand-by Operator ID: 47 07:40

Inventory Orders Results **QC** Status Utility

QC Chart Overview Test - Controls

TestCode	Lot no.	Cont.ID	Lot no.	Last Entry
TSH 0	198951	PCU1	153688	09/09/2001 15:59
TSH 0	198951	PCU1	153690	10/09/2001 13:02
TSH 0	198951	PCU2	153692	13/09/2001 14:55
TSH 0	198951	PCU2	153694	13/09/2001 09:22
TSH 0	198951	PC-THS	153511	13/09/2001 07:10
TSH 0	198951	PCU1	153696	14/09/2001 18:55
TSH 0	198951	CONTROL G	197600	15/09/2001 21:13
TSH 0	198951	CONTROL H	197604	16/09/2001 14:35
TSH 0	198951	CONTROL I	197608	21/09/2001 17:53
TSH 0	198951	CONTROL J	197612	23/09/2001 11:13

UP

Page 1/2

DOWN

Open Chart Delete Chart Close

If you open the window via the **CONTROLS** pop-up window, it has the following appearance:

The control name is displayed in the first column on the left. All tests that were measured with this control are displayed in the third column under **TestCode**.

Stand-by Operator ID: 47 07:40

Inventory Orders Results **QC** Status Utility

QC Chart Overview Control - Tests

Cont.ID	Lot no.	TestCode	Lot no.	Last Entry
PCU1	153688	TSH 0	198600	09/09/2001 15:59

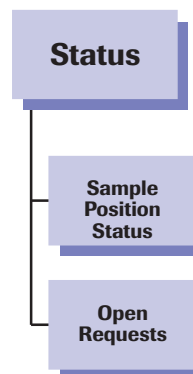
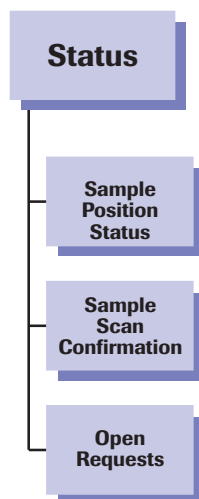
UP

Page 1/1

DOWN

Open Chart Delete Chart Close

6. STATUS



6.1 STATUS Screen

Overview of Options

The **STATUS** screen is used to monitor sample processing. It allows entry of operator ID and deletion of open requests. A sample scan is requested from this screen when using a disk system.



Stand-by Operator ID: 47 13:00

Inventory Orders Results QC Status Utility

Sample Disk Status

1 Compl	2 Compl	3 Compl	4 Compl	5 Compl
6 Compl	7 Compl	8 Compl	9 Compl	10 Compl
11 Compl	12 Incmp	13 Compl	14 Compl	15 Compl
16 Compl	17 Compl	18 Proc	19 Proc	20 Proc
21 Proc	22 Proc	23 Proc	24 Proc	25 Smpl
26 Occup	27 Occup	28 Stop	29 Empty	30 Empty

Operator ID : 47

Disk No. : 1

Last result at : 13:46

Sample Scan

Open Requests



Stand-by Operator ID: 47 14:00

Inventory Orders Results QC Status Utility

Output Area Status: Tray Part 1

					Rack ID
1 Compl	2 Compl	3 Incmp	4 Compl	5 Compl	00052
1 Compl	2 Incmp	3 Compl	4 Compl	5 Compl	00053
1 Compl	2 Compl	3 Empty	4 Empty	5 Empty	00054

Operator ID : 47

Last result at : 13:46

Open Requests

Display and Entry Fields



Disk No.

Display and entry field of the sample disk currently displayed on the screen if you are using more than one disk. To check the status of another sample disk, touch the field and type the corresponding number (0 – 9). If you are using only one disk, the digit 0 is allocated and cannot be altered.

Operator ID

Display and entry field of the laboratory-specific two-digit operator ID. Any number between 01 and 99 may be entered. The default operator ID is **01**.

Rack ID

Displays the 5-digit rack number.

Last result at:

Time when the last sample result will be completed.



Sample Disk Status

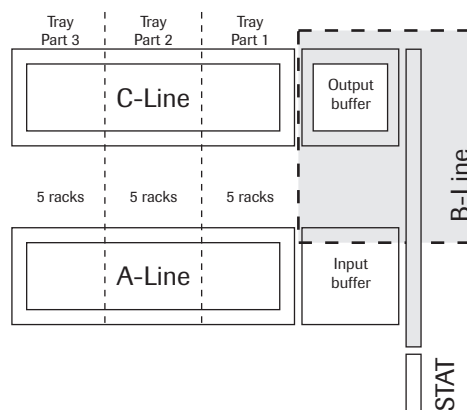
Displays the 30 positions on the sample disk. Each button depicts in text and color the current status of a sample (for a description: please refer to the table further below).

Output Area Status:

Thirty positions (six rows) are displayed on the screen, each row representing a rack.

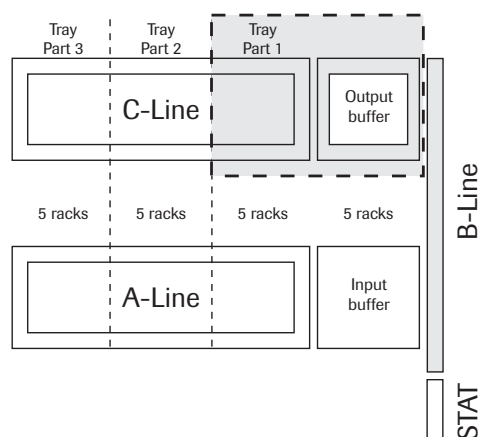
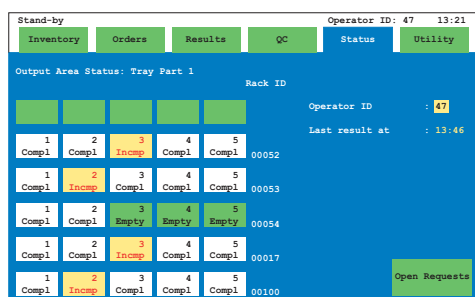
There are four status screens which relate to rack positions on the analyzer. You can move between the screens by pressing the **NEXT** and **PREV** keys.

Buffer (Screen 1)



The rack currently being processed on the B-Line is displayed on screen 1, row 1. Usually, only the rack being processed is displayed; however, if the C-Line tray is full or missing, the completed racks in the output buffer also displayed on this screen.

Tray Part 1 (Screen 2)

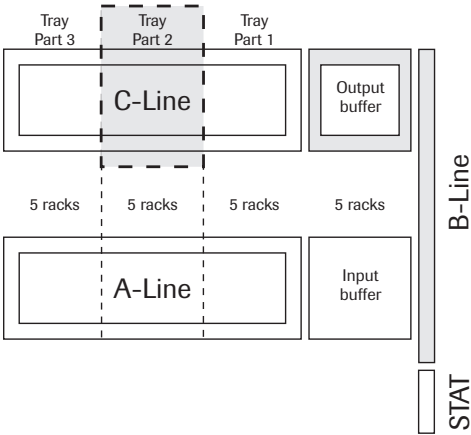


A maximum of five racks is displayed on screen 2, the first row is empty. The screen updates from top to bottom (in other words, the rack processed first appears in row 2 and continues down through 3, 4 and 5 to row 6; thereafter, it moves from screen 2, row 6 and is displayed on screen 3, row 1).

Tray Part 2 (Screen 3)

Stand-by					Operator ID: 47 13:21	
Inventory	Orders	Results	QC	Status	Utility	
Output Area Status: Tray Part 2						
					Rack ID	
1	2	3	4	5	Operator ID	: 47
Compl	Incomp	Compl	Compl	Compl	Last result at	: 13:46
1	2	3	4	5		
Empty	Empty	Empty	Empty	Compl		
1	2	3	4	5		
Compl	Incomp	Compl	Compl	Compl		
1	2	3	4	5		
Compl	Compl	Compl	Compl	Compl		
1	2	3	4	5		
Compl	Compl	Compl	Compl	Compl		
1	2	3	4	5		
Empty	Empty	Empty	Empty	Compl		

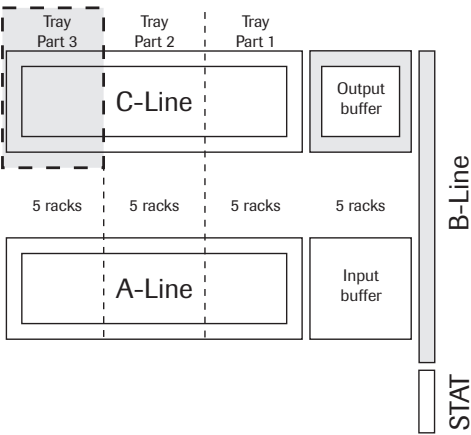
Open Requests



Screen 3 displays up to six racks. Row 1 displays the last rack from tray part 1. As with screen 2, screen 3 updates from top to bottom. When all six rows are full, screen 3, row 6 moves to screen 4, row 1. Therefore, as more racks are processed, they move into tray part 3.

Tray Part 3 (Screen 4)

Stand-by					Operator ID: 47 13:21	
Inventory	Orders	Results	QC	Status	Utility	
Output Area Status: Tray Part 3						
Rack ID						
1 Empty	2 Empty	3 Empty	4 Empty	5 Compl	Operator ID : 47	
00022					Last result at : 13:46	
1 Compl	2 Compl	3 Compl	4 Empty	5 Compl	00055	
00034						
1 Compl	2 Compl	3 Compl	4 Compl	5 Compl	00035	
00020						
1 Compl	2 Compl	3 Compl	4 Compl	5 Compl	00023	
					Open Requests	



Screen 4 displays up to six racks. Row 1 displays the last rack from tray part 2. As with screens 2 and 3, screen 4 updates from top to bottom.

Screen Buttons

26
Occup

Sample status buttons display the status of each sample on the sample disk or rack, as shown in the table below. The upper right number on the button indicates the sample's position number on the disk (up to 30) or the rack (up to 5). Touch the button to open the **SAMPLE POSITION STATUS** pop-up window, where the details of the selected sample are displayed.

System	Display	Report Text	Button Color	Text Color	Sample Status
Both	Empty	Empty	Green	Black	The position is empty and is ready for a sample.
Disk	Occup	Occupied	Lt. blue	Black	The sample position is assigned or empty (i.e., during a sample scan, the bar code reader cannot distinguish between a cup on the disk or an empty position).
Rack	Occup	Occupied	Lt. blue	Black	Rack position is occupied, but not sampled.
Both	Smpl	Active Sample	Pink	Black	Sample is currently being pipetted. On the rack system, this status is only displayed in row 1, screen 1 (Output Buffer).
Both	Proc	In process	White	Pink	The sample, control or calibrator is in process (i.e., all assays have been pipetted), but results are not ready.
Both	Incmp	Incomplete	Yellow	Red	There was an error during processing, or the sample has a result greater than the measuring range or calibration fails..
Both	Compl	Complete	White	Black	Sample/control is complete and can be removed (not for calibrators).
Disk	Stop	Stop	Red	Black	The Stop bar code was scanned.
Both	No display	STAT	Yellow	Black	A STAT sample appears yellow throughout operation.



Sample Scan

Touching this button starts a scan of the sample disk. The bar code reader is only available when the text on the button is black.

Open Requests

Opens the **OPEN REQUESTS** pop-up window where open requests can be deleted.

Print



Prints out reports on all samples on the current sample disk and their respective status.

6.2 SAMPLE POSITION STATUS Pop-up Window

You can open this window by touching a button in the **STATUS** screen. Status information concerning the selected sample position is displayed.

Stand-by					Operator ID: 47 13:00																													
Inventory	Orders	Results	QC	Status	Utility																													
<div>Sample Position Status</div> <table> <thead> <tr> <th>Test</th> <th>Dil.</th> <th>Result</th> <th>Flags</th> <th>Ready</th> <th>Type</th> <th>ID</th> </tr> </thead> <tbody> <tr> <td>TSH 0</td> <td></td> <td>5.01</td> <td>49</td> <td>12:30</td> <td>Sample</td> <td>@123</td> </tr> <tr> <td colspan="5"></td> <td>Seq.</td> <td>123</td> </tr> <tr> <td colspan="5"></td> <td>Pos.</td> <td>1 - 11</td> </tr> </tbody> </table> <div>Close</div>							Test	Dil.	Result	Flags	Ready	Type	ID	TSH 0		5.01	49	12:30	Sample	@123						Seq.	123						Pos.	1 - 11
Test	Dil.	Result	Flags	Ready	Type	ID																												
TSH 0		5.01	49	12:30	Sample	@123																												
					Seq.	123																												
					Pos.	1 - 11																												

Information Fields

The **Test** column displays the tests with which the sample or calibrators were measured, **Dil.** displays the dilution factor (if selected). The column **Result** displays the result for the test, if available. If the software is unable to calculate the result, **No Value** is displayed in this field. Any flag generated by the system during result measurement is displayed in the **Flags** column. If more than one flag is being generated during the measurement process, only the flag with the highest priority is displayed. Please refer to Chapter 2, Data Alarms in the User's Guide for a list of data flags and their descriptions. The time when the test result is expected, is displayed in the **Ready** field. No ready time is displayed for calibrators.

The type of sample is displayed in the line **Type** (Sample, Calibrator or Control). **ID** and **Seq.** identify the sample. If no ID was entered, the sequence number is displayed with an @ sign attached in the **ID** field. The sample position number (disk or rack) is displayed in the **Pos.** field.

6.3 SAMPLE SCAN CONFIRMATION Pop-up Window



Whenever you initiate a sample scan and are operating in the multiple sample disk mode, you are asked to confirm which disk is on the analyzer. This enables you to verify that the analyzer scans the desired sample disk.

Stand-by Operator ID: 47 14:00

Inventory Orders Results QC Status Utility

Sample Disk Status

1 Empty	2 Empty	3 Empty	Confirmation Current disk no. = 1 Resume Sample Scan? Resume Cancel		or ID : 47
6 Empty	7 Empty	8 Empty			o. : 1
11 Empty	12 Empty	13 Empty			esult at :
16 Empty	17 Empty	18 Empty			
21 Empty	22 Empty	23 Empty	24 Empty	25 Empty	Sample Scan
26 Empty	27 Empty	28 Empty	29 Empty	30 Empty	Open Requests

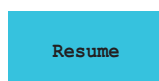
Information Fields

Displays the number of the sample disk currently loaded on the analyzer.



The sample disks are not physically numbered or coded. The disk number in use must be tracked by the operator.

Screen Buttons



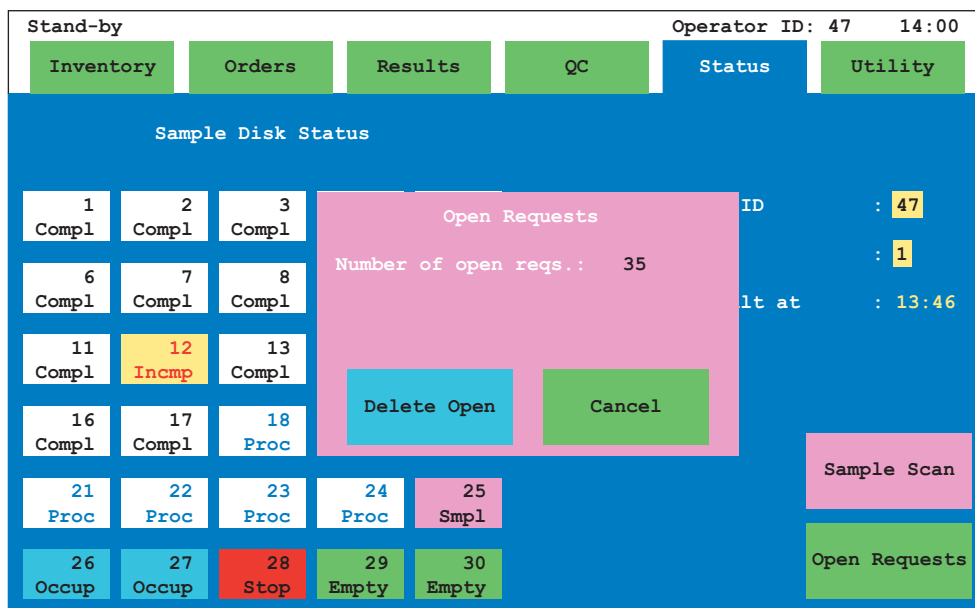
Starts the sample scan with the sample disk displayed.

6.4 OPEN REQUESTS Pop-up Window

Touch the **Open Requests** button to open this window. Open requests can be deleted here.



Open requests can only be deleted when the analyzer is in Stand-by.



Information Fields



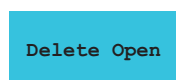
The **Number of open reqs.** field displays the number of open requests for the currently loaded disk.



The **Number of open reqs.** field displays the number of open requests in the system.

A "0" (zero) will be displayed if there are no samples in the data base or if there are samples in the data base with no test selection.

Screen Buttons



Deletes any open requests displayed in the field **Number of open reqs.** With a disk system, only the open requests for the current disk will be deleted. If **Multiple Disk** is selected, then open requests must be deleted for each disk. With a rack system, all open requests in the system will be deleted.



Disk System

When using more than one sample disk, check which disk is displayed in the **Disk Number** field.

7. UTILITY





7.1 UTILITY Screen

Overview of Options

The **UTILITY** folder offers access to test-, analyzer- and host-specific settings and maintenance functions. The **SERVICE** screen is intended solely for use by Roche service personnel and is password-protected.



Stand-by				Operator ID: 47 07:40	
Inventory	Orders	Results	QC	Status	Utility
Control Definition	Calibration Data	Test Conditions			Message History
Interface Setup	Instrument Setup	S. Disk Mode Setup			
Printout Configuration	Documen-tation Setup	Initial BlankCell		Keep Function Setup	
Maintenance	Temperature Monitor	Voltage Monitor		Retry Function Setup	
Assay Perf. Check	Mechanism Check	Automatic Adjustment			Service



Stand-by				Operator ID: 47 07:40	
Inventory	Orders	Results	QC	Status	Utility
Control Definition	Calibration Data	Test Conditions			Message History
Interface Setup	Instrument Setup				
Printout Configuration	Documen-tation Setup	Initial BlankCell		Keep Function Setup	
Maintenance	Temperature Monitor	Voltage Monitor		Retry Function Setup	
Assay Perf. Check	Mechanism Check	Automatic Adjustment			Service

7.2 CONTROL DEFINITION 1 Screen

You can define a maximum of 15 controls (Roche and non-Roche controls) here. The screen only displays data when controls have been scanned in and selections made.

Stand-by Operator ID: 47 07:40

Control Definition Utility

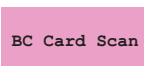
Control no. : Lot no. : BC Card Scan Controls

Control ID : Exp. date :



This screen never displays any data when opened via the **UTILITY** screen. Only the buttons **BC CARD SCAN** and **CONTROLS** are available for use.

Screen Buttons



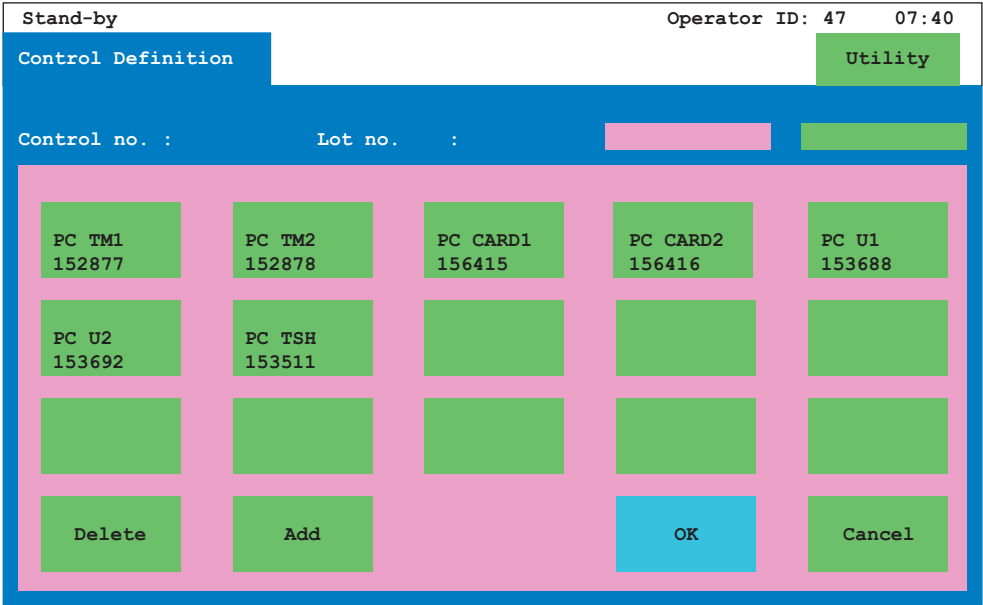
Touch this button to scan in bar code cards of controls placed in the card reading station. This button is available if the text on the button is black. If the text on the button is white, then the bar code reader is not available.



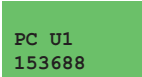
Touch this button to access the **CONTROL DEFINITION** pop-up window, where all Roche and manually entered non-Roche controls are displayed, and available for definition and selection.

7.2.1 CONTROL DEFINITION Pop-up Window

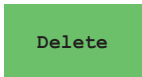
This pop-up window is opened by touching the **CONTROLS** button in the **CONTROL DEFINITION 1** screen. All Roche controls and manually entered non-Roche controls (max. 15) are displayed. Controls can also be deleted or added. If 15 controls are stored, it will be necessary to delete one before scanning-in or entering a new control.



Window Buttons



Following the selection of a control (button changes color from green to light blue), the control and the corresponding test are displayed in the **CONTROL DEFINITION** screen.



Opens the **DELETE CONTROL** pop-up window following selection of a control.



To define non-Roche controls, touch an empty control button and then open the **ADD CONTROL** pop-up window.

Print



Prints out the control definition for the selected control.

7.3 CONTROL DEFINITION 2 Screen

After selecting a control and touching **OK** in the **CONTROL DEFINITION** pop-up window, the **CONTROL DEFINITION 2** screen opens. It displays all tests that can be measured with the control indicated above the tests.

Stand-by		Operator ID: 47		07:40	
Control Definition			Utility		
Control no. : 1		Lot no. : 153688		BC Card Scan	
Control ID : PC U1		Exp. date : 03/2003		Controls	
10 TSH 0	21 T4 1	30 FT4 0	40 T-UP 0	50 T3 0	60 FT3 0
102 E2 2	110 TESTO 0	120 PROG 0	130 PRL 0	140 LH 0	150 FSH 0
170 HCGSTAT 0	180 HCG 0	260 DIGIT 0	300 CEA 0	310 AFP 0	380 FERR 0
610 FOL 0	620 DIGO 0	630 IGE 0	650 INSULIN 0	700 TG 0	740 DHEA-S 0
					760 HCG-BETA 0

Display Fields

The following information is displayed after scanning and selecting a control.

- **Control no.** Roche controls cannot be altered (1 to 63). Numbers for non-Roche controls must be manually assigned (64 to 78).
- **Control ID**, **Lot no.** and expiration date (**Exp. date**) for the control is displayed.

Screen Buttons

BC Card Scan

Touch this button to scan in bar code cards for controls which are placed in the card reading station. This button is available if the text on the button is black. If the text on the button is white, then the bar code reader is not available.

Controls

Touch this button to access the **CONTROL DEFINITION** pop-up window, where all Roche and manually entered non-Roche controls are displayed and available for definition and selection.

10
TSH 0

Test buttons for all tests that can be measured with the displayed control. The control must previously have been selected in the **CONTROL DEFINITION** pop-up window before the tests can be displayed here. After touching a test button (the color changes from green to light blue), the test and the displayed control are selected for the next measurement. When a light blue test button is touched (selected test) the according **CONTROL DEFINITION DETAILS** pop-up window (Roche or non-Roche control) is opened. The test buttons are displayed in the same order as the test numbers on the screen. If a test number has been changed, the test is sorted in the **INVENTORY** and the **TEST CONDITIONS** screens according to the new number.



If a test number is altered in the **CONTROL DEFINITION DETAILS** pop-up window, the new number is displayed on the test button. However, the test buttons remain in the previous order on the screen.

7.3.1 CONTROL DEFINITION DETAILS Pop-up Window

This pop-up window is opened by touching the button of a test in the **CONTROL DEFINITION 2** screen. As well as displaying control/test combination details (e.g., target value), you can choose whether the control is to be available for the selected test during normal operations via **Preselection**.

The appearance and the content of the pop-up window depend upon whether a Roche control or a non-Roche control is selected.

Test related Overview Pop-up Window (Roche Control)

Display Fields

The number, code and unit of the selected test are displayed.

Window Buttons

155004
0.910

Displays a maximum of 15 test lots with the corresponding lot numbers and target values for the selected test. After touching a button, the **CONTROL DEFINITION DETAILS 1** pop-up window opens where the target value can be altered.

Active

Press this button to activate the test for the control (color changes to light blue) so that it is available for the selected test during normal operations (**Preselection**).

Inactive

Press this (light blue) button to deactivate the test for the control so it is **not** available for the selected test during normal operations (**Preselection**).

CONTROL DEFINITION DETAILS 1 (Roche Controls)

This pop-up window is opened by touching a test button in the **TESTRELATED OVERVIEW** pop-up window. As well as displaying test details, it is possible to alter the target values here. Control results are validated using these values.

Stand-by		Operator ID: 47 07:40	
Control Definition		Utility	
Control no.: 1	Lot no.: 190599	BC Card Scan	Controls
Control ID : PCU1			
10 TSH 0	21 T4 1	Test no., Code : 10 TSH 0 Assay Lot No. : 150093 Target value, range : 1.39 30 Target lower/upper : 0.973 - 1.81 Unit : uIU/ml OK Cancel	
102 E2 2	110 TESTO	3 0	100 E2 0
170 HCGSTAT 0	180 HCG 0	0 H 0	160 CORT 0
610 FOL 0	620 DIGO	0 RR 0	600 B12 0
		0 EA-S 0	760 HCG-BETA 0

Display and Entry Fields

- Test- and control-specific details:
Test number, test code, lot number of the test and the unit in which the results are displayed. The **Target value lower/upper** fields display the lower and upper target values. These values are calculated using the values in the **Target value** and **range** fields.

Target value, range

Display and entry of control target value (first field) and range (second field) for the selected test. The control range (second field) is displayed as a percentage and is subtracted from and added to the target value automatically. For example, the value 25 means the control range is 25% either side of the target value.

CONTROL DEFINITION DETAILS 2 (non-Roche Controls)

This pop-up window is opened by touching a button displaying a non-Roche control (**CONTROL DEFINITION** pop-up window), which was entered previously in the **ADD CONTROL** pop-up window.

The screenshot shows the 'CONTROL DEFINITION 2 Screen' with a blue header bar. The header contains 'Stand-by' on the left, 'Operator ID: 47' and '07:40' on the right, and a 'Utility' button. Below the header is a 'Control Definition' section with a blue background. It displays 'Control no. : 70', 'Lot no. : 197600', and 'Control ID : CONTROL G'. To the right of this section is a 'BC Card Scan' button and a 'Controls' button. A pink pop-up window is centered on the screen, displaying the following fields: 'Test no., code : 10 TSH 0', 'Target value, range : 2.25 25', 'Target lower/upper : 1.69 - 2.81', 'Unit : uIU/ml', and 'Preselection : Active Inactive'. At the bottom of the pop-up are 'OK' and 'Cancel' buttons.

Display and Entry Fields

Test no., code

Display and entry of the test number of the selected non-Roche control. The code for the selected test is displayed in the second field.



The test for the test code applied must have been registered once in the system.

Target value, range

Display and entry of the control target value (first field) and control range (second field) for the selected test. The control range is displayed in percentages and is subtracted from and added to the target value. For example, the value 25 means the control range is 25% either side of the target value.

- Test- and control-specific details:

The **Unit** of the test can be altered in the **TEST CONDITIONS** pop-up window (**UTILITY** folder). The Target value lower/upper fields display the lower and upper target values. These values are calculated using the values in the **Target value** and **range** fields.

Window Buttons

Active

Press this (light blue) button to activate the control so it is available for the selected test during normal operations (**Preselection**).

Inactive

Press this (light blue) button to deactivate the control so it is **not** available for the selected test during normal operations (**Preselection**).

7.3.2 ADD CONTROL Pop-up Window

This pop-up window is opened by touching an empty control button followed by **Add** in the **CONTROL DEFINITION** pop-up window. Here you can enter non-Roche controls.

Display and Entry Fields

Depending on the number entered in the **Control no.** field the control name is displayed in the **Control ID** field.

Control no.

Enter the non-Roche control number (64 to 78)



Control number assignment

1 to 63 reserved for Roche controls

64 to 66 Lyphochek 1, 2, 3

67 to 69 Liquichek 1, 2, 3

70 to 78 freely assignable (Control G to Control O)

Lot no.

Enter the lot number of the non-Roche control in this field.

Exp.year/month

Enter the expiration date of the non-Roche control.

7.3.3 DELETE CONTROL CONFIRMATION Pop-up Window

This pop-up window appears after you touch a control button followed by the **DELETE** button in the **CONTROL DEFINITION** pop-up window. Here you can confirm your decision to delete a control.

Stand-by Operator ID: 47 07:40

Control Definition Utility

Control no. :
Control ID :

Confirmation

Delete this control data?

Control no. : 6
Control ID : PCTM1
Lot no. : 152877

OK Cancel

Scan Controls

Display Fields

Display the **Control no.**, name (**Control ID**) and **Lot no.** of the control to be deleted.

7.4 CALIBRATION DATA Screen

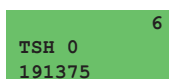
Displays a list of all calibrated tests with their lot numbers. The color of the buttons indicates the calibration status. Green buttons indicate successful calibrations, yellow buttons indicate questionable calibrations and red buttons indicate failed calibrations. Test codes are displayed in test number order.

Stand-by Operator ID: 47 07:40

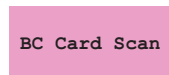
Calibration Data Utility

TSH 0 191375	T4 1 189844	T3 0 191210	HCGSTAT 0 194538	CEA 1 195005
AFP 1 192889	PSA 1 191898	FERR 0 194415	B12 0 192905	FOL 0 194538
DIG 0 190451				
				BC Card Scan

Screen Buttons



Each test button lists the lot number currently in use as well as the test generation number next to the test code name. Test buttons are sorted first by test number. Touch a button to access the **CALIBRATION DATA DETAILS** pop-up window, which displays calibration-specific details for the selected test.



Touch this button (pink with black text) to initiate a calibrator bar code card scan. Bar codes cannot be scanned in when the text on the button is white. The bar code card must remain in the card reading station until an audible signal indicates that scanning was successful.

Print



- If no test is selected (no light blue button), press this key to obtain a calibration data report for all assays.
- If a test is selected (button is light blue), press this key to obtain a calibration data report for the selected assay.

7.4.1 CALIBRATION DATA DETAILS Pop-up Window

Touch a test button in the **CALIBRATION DATA** screen to open this window. A calibration can be released or rejected, depending on its status. This window displays reagent and reagent lot-specific information for the test, status messages concerning the calibration and criteria concerning the quality of the calibration. Individual fields differ depending on whether a quantitative or qualitative test is displayed.

Stand-by		Operator ID: 47 07:40	
Calibration Data		Utility	
Test code : HCGSTAT 0 Lot calibration was succesful		Calibration Quality Criteria Lot no. calibrator : 194538 Missing values ----- Monotony of curve ----- Calibration factor 1.0 ----- Minimum signal ----- Minimum accept. difference ----- Deviation of dupl. ----- System errors -----	
TS 19	L-Cal date : 05/13/2001 Reagent pack no. : 718 Lot no. calibrator : 192927 Exp. date : 05/2001 Recommended at : 06/12/2001	Cal. 1.signal 2.signal Target 1: 2627 2613 8.98 2: 720229 712953 4690	4
E2 19	R-Cal date : 05/13/2001 Reagent pack no. : 718 Lot no. calibrator : 192927 Exp. date : 05/2001 Recommended at : 05/20/2001		9
HC 19			11
PS 19	Release Reject OK Cancel		an

Display Fields

The left side of the screen displays the **Test code**, possible calibration statuses (see table below) and specific fields for reagent and reagent lot calibration. The right side of the screen displays criteria concerning the quality of the calibration. These vary depending on whether a quantitative or qualitative test has been selected.

- Reagent pack and reagent lot-specific fields for both types of calibration: Date of the last successful calibration (**L-Cal date** and **R-Cal date**), **Reagent pack no.**, **Lot no. calibrator** and expiration date (**Exp. date**).

The **Recommended at** field indicates the date at which the next L-Cal or R-Cal calibration is recommended. High volume reagent users (reagent pack used in less than seven days) should follow the **L-Cal date** recommendation. Lower volume users (reagent pack in use for more than seven days) should follow the **R-Cal date** recommendation.

- Calibration status displays

Status message	Meaning
Lot calibration was successful	The calibration was successful and has been stored in the system as an L-Cal.
Reagent pack calibration was successful	The calibration was successful and has been stored in the system as an R-Cal.
R. pack on analyzer > 24 hours Released as R.pack calibration by system	The calibration was not accepted as an L-Cal. The system has released the calibration as an R-Cal. The reagent pack used for calibration was on the analyzer for more than 24 hours since its registration. The calibration is valid only for this reagent pack. An L-Cal can only be generated with a reagent pack that has been on the analyzer for less than 24 hours since its registration.
Lot calibration not successful Released as R.pack calibration by operator	The calibration was not accepted as an L-Cal. The initial calibration was questionable, but was released by the operator. This calibration is valid only for this reagent pack.
R.pack calibration questionable Released as R. pack calibration by operator	The attempted calibration was questionable, but was released by the operator. This calibration is valid only for this reagent pack.
This calibration cannot be released	An L-Cal was attempted on a new assay or new reagent lot, but the calibration failed. Since this is a new assay or new reagent lot there is no previous calibration data to which to revert.
Lot calibration not successful	The attempted L-Cal was not successful, but a previous valid calibration exists in the system. The system reverted to the previous calibration to calculate sample results.
Reagent pack calibration not successful	The attempted R-Cal was not successful, but a valid L-Cal exists in the system. The system reverted to the previous calibration to calculate sample results.
Calib with expired reagent pack	This message can be combined with any other previously described calibration messages with the exception of Lot calibration was successful .

Calibration Quality Criteria for Quantitative Tests

Stand-by		Operator ID: 47 07:40	
Calibration Data		Utility	
Test code : HCGSTAT 0 Lot calibration was succesful		Calibration Quality Criteria Lot no. calibrator : 194538 Missing values ----- Monotony of curve ----- Calibration factor 1.0 ----- Minimum signal ----- Minimum accept. difference ----- Deviation of dupl. ----- System errors -----	
TS 19	L-Cal date : 05/13/2001 Reagent pack no. : 718 Lot no. calibrator : 192927 Exp. date : 05/2001 Recommended at : 06/12/2001	Cal. 1.signal 2.signal Target 1: 2627 2613 8.98 2: 720229 712953 4690	4
E2 19	R-Cal date : 05/13/2001 Reagent pack no. : 718 Lot no. calibrator : 192927 Exp. date : 05/2001 Recommended at : 05/20/2001		9
HC 19			11
PS 19	<input type="button" value="Release"/> <input type="button" value="Reject"/> <input type="button" value="OK"/> <input type="button" value="Cancel"/>		an

Lot no. calibrator

The lot number of the assay's CalSet calibrators used for the calibration in question. This is not a quality criterion.

Missing values

Duplicate determinations of two calibrators are used to adjust the master calibration curve stored on the reagent pack bar code. Therefore, you must have a minimum of n-1 values for all calibrator replicates measured (n = total number of calibrator replicates. For any current Elecsys assay, this number totals 4.). If all calibrator replicates were sampled with no errors, this field displays 10 dashes for quantitative assays and 4 dashes for qualitative assays. You only see information in the first four, representing Cal 1 and Cal 2. Currently, all Elecsys reagents utilize only two calibrators. This field can accommodate up to five calibrators.

Check to see if any alarms occurred during calibration that may have caused the missing values. Treat any questionable calibration according to laboratory policy.

Field display	n	Would result in a...	Test button color
-----	4	successful calibration	green
1-----	3	questionable calibration	yellow
-1-----	3	questionable calibration	yellow
-2-----	3	questionable calibration	yellow
-2----	3	questionable calibration	yellow
11-----	2	failed calibration	red
-22----	2	failed calibration	red
1-2-----	2	failed calibration	red
1-2----	2	failed calibration	red
-12-----	2	failed calibration	red
-1-2----	2	failed calibration	red
112-----	1	failed calibration	red
11-2----	1	failed calibration	red
1-22----	1	failed calibration	red
-122----	1	failed calibration	red
1122----	0	failed calibration	red

Monotony of curve

All measured calibrator values must fall in ascending (sandwich or bridging principle) or descending (competition principle) order. This is termed monotony. This field displays five dashes representing up to five calibrators. If either a 1 (Cal 1) or a 2 (Cal 2) is displayed in this field, the result is a failed calibration. Errors in the monotony curve may occur if, for example, calibrators without bar code labels have been frozen in small portions and later filled into the wrong calibrator vials.

Calibration factor

A curve position check against the most recent lot calibration produces a calibration factor. This field displays a number that represents this factor. Each new lot calibration (L-Cal) utilizes a calibration factor of 1. For all subsequent reagent pack calibrations (R-Cal), a new calibration factor is calculated. The calibration factor is the quotient of the slopes of the actual performed calibration and the related stored calibration.



The calibration factor criterion is only used in validating R-Cals.

Calibration factor (x)	Would result in a...	Test button color
$x = 0.8 - 1.2$	successful calibration	green
$x = 0.6 - 0.79$ OR $x = 1.21 - 1.4$	questionable calibration	yellow
$x < 0.6$ OR $x > 1.4$	failed calibration	red

Calibration Factor Calculation

Each lot calibration utilizes a calibration factor 1. The following reagent pack calibrations are compared with the last measured lot calibration.

The calibration factor is the ratio between the calibrator signals (difference of CalSet 1 and CalSet 2) of the lot and rackpack calibration.

The calibration factor is only used as a calibration validation criteria and not used for sample calculation.

$$\text{Calibration factor for each Lot calibration} = \frac{t_l}{t_l} = 1$$

$$t_l (\text{slope}) = \frac{\text{CalSet 1 signal (standardization)} - \text{CalSet 2 signal (standardization)}}{\text{actual CalSet 1}_l \text{ signal} - \text{actual CalSet 2}_l \text{ signal}}$$

$$t_r (\text{slope}) = \frac{\text{CalSet 1 signal (standardization)} - \text{CalSet 2 signal (standardization)}}{\text{actual CalSet 1}_r \text{ signal} - \text{actual CalSet 2}_r \text{ signal}}$$

Calibration factor for Reagent pack calibration =

$$\frac{t_l}{t_r} = \frac{\text{actual CalSet 1}_r \text{ signal} - \text{actual CalSet 2}_r \text{ signal}}{\text{CalSet 1}_l \text{ signal} - \text{CalSet 2}_l \text{ signal}}$$

$$\text{Example: Elecsys® TSH} = \frac{1000 - 22000 \text{ counts}}{1100 - 25000 \text{ counts}} = 0.88$$

r = Reagent pack calibration

l = Lot calibration

Minimum signal

The measured signal of the calibrator replicate must be above the minimum value. Values are test dependent and are encoded in the reagent bar code. If all calibrator replicates were sampled with no errors, this field displays 10 dashes. You only see information in the first four, representing Cal 1 and Cal 2. Currently, all Elecsys reagents utilize only two calibrators. This field can accommodate up to five calibrators.

Field display	Would result in a...	Test button color
-----	successful calibration	green
1-----	questionable calibration	yellow
-1-----	questionable calibration	yellow
-2-----	questionable calibration	yellow
-2----	questionable calibration	yellow
11-----	failed calibration	red
-22----	failed calibration	red
1-2-----	failed calibration	red
1-2----	failed calibration	red
-12-----	failed calibration	red
-1-2----	failed calibration	red
112-----	failed calibration	red
11-2----	failed calibration	red
1-22----	failed calibration	red
-122----	failed calibration	red
1122----	failed calibration	red

Minimum acceptable difference

The difference in percent between calibrator 1 and 2. This difference must amount to at least 30 % for the calibration to be accepted. The minimum acceptable difference is listed as OK or Not OK.

Deviation of dupl.

The deviation of duplicate measurements is a check of the signal values for each replicate of a calibrator. If the difference between the duplicate measurements is too great, the appropriate calibrator is flagged. The signal values listed in the **Cal.** field are used to calculate the mean value of the duplicate measurements. This field displays five dashes, representing up to five calibrators.

Field display	Would result in a...	Test button color
---	successful calibration	green
1--	questionable calibration	yellow
-2--	questionable calibration	yellow
12--	failed calibration	red

System errors

A hardware error occurred during a calibrator measurement. This field displays five dashes representing up to five calibrators. If either 1 (Cal 1) or 2 (Cal 2) appear in this field, the result is a failed calibration.

Cal.**1. Signal**

The actual signal of the first measurement of Cal 1 or Cal 2. The mean of the first and second measurements is used in the calculation of the calibration curve.

2. Signal

The actual signal of the second measurement of Cal 1 or Cal 2. The mean of the first and second measurements is used in the calculation of the calibration curve.

Target

The target values of the calibrators encoded in the CalSet calibrator bar code card.

Calibration Quality Criteria Table for Quantitative Assays

Color	Calibration Status	Criteria
green	successful R-Cal ONLY *	<ul style="list-style-type: none"> no values are missing all values are above the recommended minimum signal level there are no duplicate errors calibration factor is within acceptable range (0.8 - 1.2)
yellow	questionable R-Cal ONLY*	<ul style="list-style-type: none"> one of either calibrator's duplicate values is missing one of either calibrator's duplicate values is below the recommended minimum signal level one calibrator level was measured with a duplicate error (i.e., the signal difference between the two calibrator determinations is too high) the calibration factor is: 0.6 - 0.79 OR 1.21 - 1.4
red	failed R-Cal ONLY*	<ul style="list-style-type: none"> two or more of the calibrator's replicate values are missing two or more of the calibrator's replicate values are below the recommended minimum signal level two calibrator levels were measured with a duplicate error (i.e., the signal difference between the two calibrator determinations is too high) failure of monotony (e.g., measured calibrator values were not in either ascending or descending order) calibration factor is out of range (Cal factor < 0.6 OR Cal factor > 1.4)

* The calibration factor is a criterion used only for R-Cals.

Calibration Quality Criteria for Qualitative Tests

Stand-by		Operator ID: 47 07:40													
Calibration Data		Utility													
Test code : A-HBC Lot calibration not succesful Calib with expired reagent pack I-Cal date : Reagent pack no. : Lot no. calibrator : Exp. date : Recommended at : R-Cal date : Reagent pack no. : Lot no. calibrator : Exp. date : Recommended at :		Calibration Quality Criteria Lot no. calibrator : 194528 Missing values ---- Slope OK Min/max signal ---- Minimum accept. difference OK Deviation of dupl. 1- System errors -- <table border="1"> <thead> <tr> <th>Cal.</th> <th>1.signal</th> <th>2.signal</th> <th>Target</th> </tr> </thead> <tbody> <tr> <td>1:</td> <td>49042</td> <td>61171</td> <td></td> </tr> <tr> <td>2:</td> <td>622.8</td> <td>630.4</td> <td></td> </tr> </tbody> </table> Cutoff : 39207 Borderline : 1.00 - 1.00		Cal.	1.signal	2.signal	Target	1:	49042	61171		2:	622.8	630.4	
Cal.	1.signal	2.signal	Target												
1:	49042	61171													
2:	622.8	630.4													
Release Reject OK Cancel		an													

Lot no. calibrator

The lot number of the assay's CalSet calibrators used for the calibration in question. This is not a quality criterion.

Missing values

Duplicate determinations of two calibrators are used to adjust the master calibration curve stored on the reagent pack bar code. Therefore, you must have a minimum of n-1 values for all calibrator replicates measured (n = total number of calibrator replicates. For any current Elecsys assay, this number totals 4.). If all calibrator replicates were sampled with no errors, this field displays 10 dashes for quantitative assays and 4 dashes for qualitative assays. You only see information in the first four, representing Cal 1 and Cal 2. Currently, all Elecsys reagents utilize only two calibrators. This field can accommodate up to five calibrators.

Check to see if any alarms occurred during calibration that may have caused the missing values. Treat any questionable calibration according to laboratory policy.

Field display	n	Would result in a...	Test button color
-----	4	successful calibration	green
1-----	3	questionable calibration	yellow
-1-----	3	questionable calibration	yellow
-2-----	3	questionable calibration	yellow
-2----	3	questionable calibration	yellow
11-----	2	failed calibration	red
-22----	2	failed calibration	red
1-2-----	2	failed calibration	red
1-2----	2	failed calibration	red
-12-----	2	failed calibration	red
-1-2----	2	failed calibration	red
112-----	1	failed calibration	red
11-2----	1	failed calibration	red
1-22----	1	failed calibration	red
-122----	1	failed calibration	red
1122----	0	failed calibration	red

Slope

All measured calibrator values must fall in ascending (sandwich or bridging principle) or descending (competition principle) order. The slope of the current calibration is listed as OK or Not OK.

Min/max signal

The measured signal of the calibrator should be between the designated minimum and maximum signal. Minimum and maximum signals are test dependent and are encoded in the reagent bar code. If all calibrator replicates were sampled with no errors, this field displays four dashes, representing the calibrator replicates.

Field display	Would result in a...	Test button color
--	successful calibration	green
1--	questionable calibration	yellow
-1-	questionable calibration	yellow
-2-	questionable calibration	yellow
-2	questionable calibration	yellow
11-	failed calibration	red
-22	failed calibration	red
1-2-	failed calibration	red
1-2	failed calibration	red
-12-	failed calibration	red
-1-2	failed calibration	red
112-	failed calibration	red
11-2	failed calibration	red
1-22	failed calibration	red
-122	failed calibration	red
1122	failed calibration	red

Minimum acceptable difference

The difference between the negative and positive calibrator signal values must be greater than the allowable value limit. This limit is test dependent and is encoded in the reagent bar code. The minimum acceptable difference is listed as OK or Not OK.

Deviation of dupl.

The deviation of duplicate measurements is a check of the signal values for each replicate of a calibrator. If the difference between the duplicate measurements is too great, the appropriate calibrator is flagged. The signal values listed in the **Cal.** field are used to calculate the mean value of the duplicate measurements. This field displays five dashes, representing up to five calibrators.

Field display	Would result in a...	Test button color
----	successful calibration	green
1---	questionable calibration	yellow
-2---	questionable calibration	yellow
12---	failed calibration	red

System errors

A hardware error occurred during a calibrator measurement. This field displays five dashes representing up to five calibrators. If either 1 (Cal 1) or 2 (Cal 2) appear in this field, the result is a failed calibration.

Cal.**1. Signal**

The actual signal of the first measurement of Cal 1 or Cal 2. The mean of the first and second measurements is used in the calculation of the calibration curve.

2. Signal

The actual signal of the second measurement of Cal 1 or Cal 2. The mean of the first and second measurements is used in the calculation of the calibration curve.

Cutoff

Qualitative assays are calibrated by a scaling factor, the so-called cutoff value. The actual cutoff value is calculated with the cutoff formula, by using the mean values of the low calibrator signals and the mean values of high calibrator signals of one high and one low value. Each sample receives a scaled result value, the cutoff index, which allows for the classification of samples being reactive or non-reactive (in other words, the cutoff index is greater than or less than 1).

$$\text{Cutoff index} = \frac{\text{measured signal}}{\text{cutoff value}}$$

Borderline

For some assays it is possible that in a range around a Cutoff Index = 1, no determination regarding reactive or non-reactive results can be made. This range is called the borderline or borderline area.

Calibration Quality Criteria Table for Qualitative Assays

Color	Calibration Status	Criteria
green	successful	<ul style="list-style-type: none"> no values are missing the slope is within the bar-coded parameters all values are greater than the minimum signal and less than the maximum signal the difference between the negative calibrator and positive calibrator's signal values is greater than the allowable value there are no duplicate errors there are no system errors
yellow	questionable	<ul style="list-style-type: none"> one of either calibrator's duplicate values is missing one of either calibrator's duplicate values is out of the allowable minimum/maximum signal range (i.e., one value is less than the minimum signal or greater than the maximum signal) one calibrator level was measured with a duplicate error (i.e., the signal difference between the two calibrator determinations is too high)
red	failed	<ul style="list-style-type: none"> two or more of the calibrator's replicate values are missing the slope is not within the bar-coded parameters two or more of the calibrator's replicate values are out of the allowable minimum/maximum signal range (i.e., two or more values are less than the minimum signal or greater than the maximum signal) the difference between the negative calibrator and positive calibrator's signal values is less than or equal to the allowable value two calibrator levels were measured with a duplicate error (i.e., the signal difference between the two calibrator determinations is too high)

Window Buttons



Touch this button to release a questionable calibration manually (yellow test button, **CALIBRATION** screen). This button is only available if it is light blue. Refer to your Calibration Data report for the assay or the data on the window to determine if the calibration can be released. Manual release always results in an R-Cal.



Follow your laboratory protocol regarding questionable or failed calibration results.

Reject

Touch this button to manually reject (delete) a questionable (yellow button) or failed (red button) calibration manually (**CALIBRATION** screen). This button is only available if it is light blue.

The last valid calibration is used to calculate results for subsequent samples. The calibration should be repeated.

Print



Press this key to obtain a calibration data report for the displayed assay.

7.5 TEST CONDITIONS Screen

Displays buttons with test codes and test numbers of the previously scanned tests. Touch one of these buttons to open the **TEST CONDITIONS DETAILS** pop-up window for the selected assay, where test specific values can be viewed and altered.

Stand-by		Operator ID: 47 07:40		
Test Conditions		Utility		
TSH 0 10	T4 1 21	T3 0 50	HCGSTAT 0 170	CEA 1 301
AFP 1 311	PSA 1 321	FERR 0 380	B12 0 600	FOL 0 610
DIG 0 620				

Screen Buttons

T4 1 21

Displays the tests with test code and test number.

Print



Press this key to obtain a Test Conditions report for all test buttons currently on the screen.



We recommend that you do not change the test number if your analyzer is interfaced to a host. The number utilized by the host interface remains the same as the one encoded in the reagent bar code. This number appears in **INVENTORY** once the software is loaded.

7.5.1 TEST DETAILS Pop-up Window

Open this window by touching a test button on the **TEST CONDITIONS** screen. This window provides assay-specific information that can be altered.

Display and Entry Fields

The **Test code** field displays the name of the selected test. The **Diluent lot no.** field only then displays the diluent lot number if the diluent is on the analyzer and the test can be diluted.

Test no.

The test number encoded in the reagent bar code label. The test number can be redefined by the user to utilize it as a sorting and workflow criterion. A number from 1 to 999 may be assigned; each number can be assigned once only. The test number that is assigned in this window appears on the QC screen, the alarm screen and on the message history printout.



Caution

The non-redefinable test numbers assigned by Roche are scanned in from the reagent pack bar code for utilization by the host.

Unit

Up to three units are displayed here. The available units for the assay are encoded in the reagent bar code. You can select a different unit by touching the appropriate text. The selected unit is highlighted in a light blue field. Only those units encoded in the reagent bar code can be utilized by the analyzer.

Exp. value Lower limit

Exp. value Upper limit

Display and entry for the lower and upper limit values encoded in the reagent bar code. Each value can be altered individually.

Instrument factor A**Instrument factor B**

Entry and display for the analyzer correction factors. These two fields correspond to slope (A) and intercept (B). Using these factors, results measured by the analyzer can be adjusted to a laboratory specific reference range. The default settings are “1.00” for A and “0.000” for B.

Threshold

In this field you can define the number of tests at which you want notification in the **INVENTORY** screen that the reagent is running low. The default for this field is 0. If the number falls below the set value, then the corresponding test button turns yellow and a **T** is displayed.

Expected values check

If **On** is selected, patient results are checked against the expected values, the reference range is printed on the reports and the result is flagged if necessary. If **Off** is selected, the expected value fields are blank and any alarms are not sent to the host.

The selected test choice appears in a light blue field. The default choice is **On**. **Off** is used for qualitative tests.

Daily calib request

If **On** is selected, the corresponding test is flagged in the **INVENTORY** screen that a daily calibration is necessary. The test button is yellow and displays **RC**. The default for the **Daily calib request** field is **Off**. This field should only be necessary for assays that require daily calibration.

Diluent factor

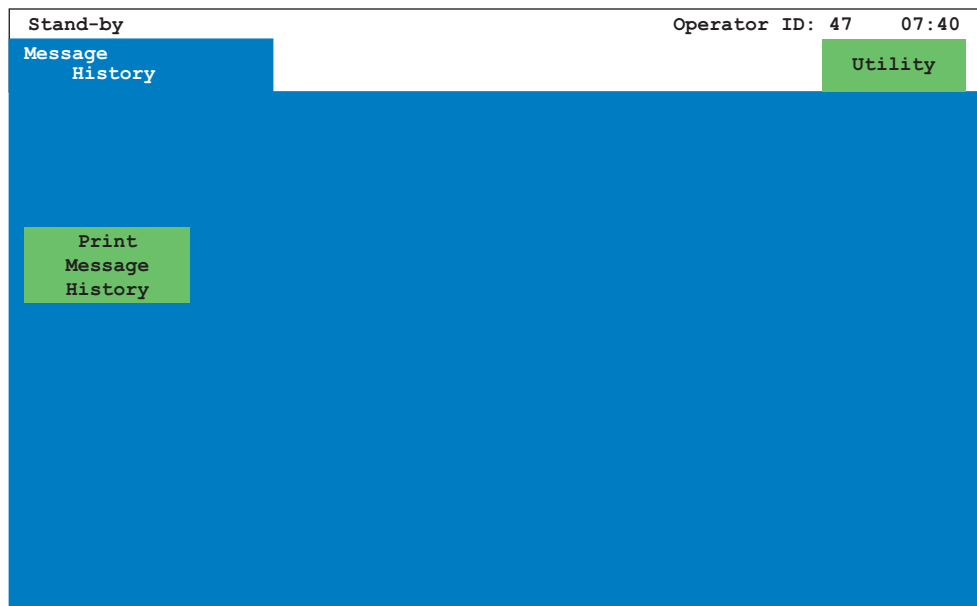
Here you can preset a dilution factor for an assay. **All** samples requested for this assay are automatically diluted by the dilution factor selected here. Calibrators and controls are not diluted.

Print

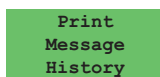
Press this key to obtain a **Test Conditions** report for the test displayed in the pop-up window.

7.6 MESSAGE HISTORY Screen

This screen displays a button to print out a summary of alarm messages on the analyzer and if required print them out.



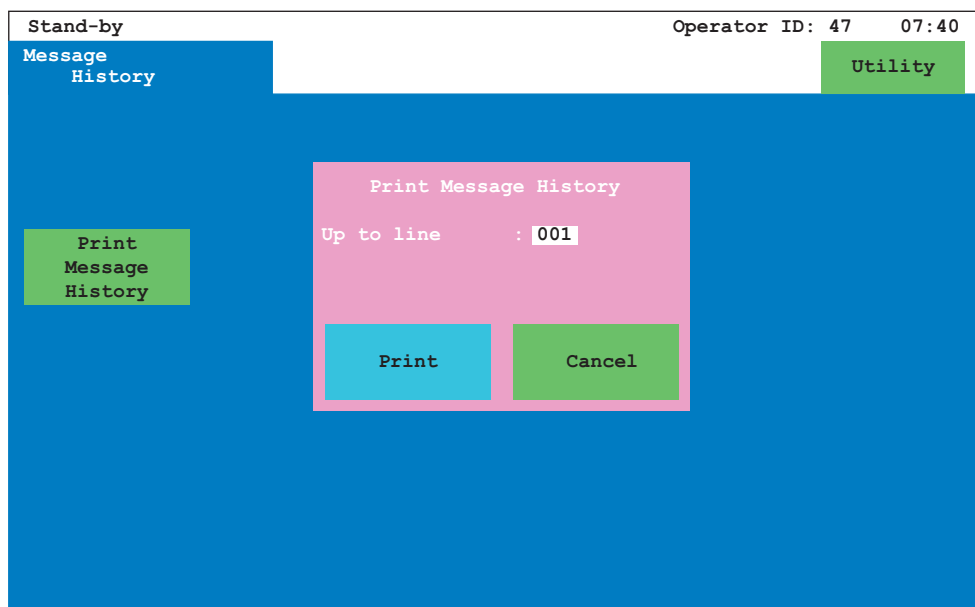
Screen Buttons



Touch this button to access the **PRINT MESSAGE HISTORY** pop-up window.

7.6.1 PRINT MESSAGE HISTORY Pop-up Window

This window is opened by touching the **PRINT MESSAGE HISTORY** button and allows you to print a list of all alarm messages that have occurred on the system. The system holds up to 200 messages. After that, the alarms are replaced on a first in, first out (FIFO) basis.



The message history can only be printed out, but not viewed on screen.

Entry Fields

Up to line:

Type the number of messages you want printed. You can enter a number from 1 to 200. The default is 1. The most recent alarm is printed first.

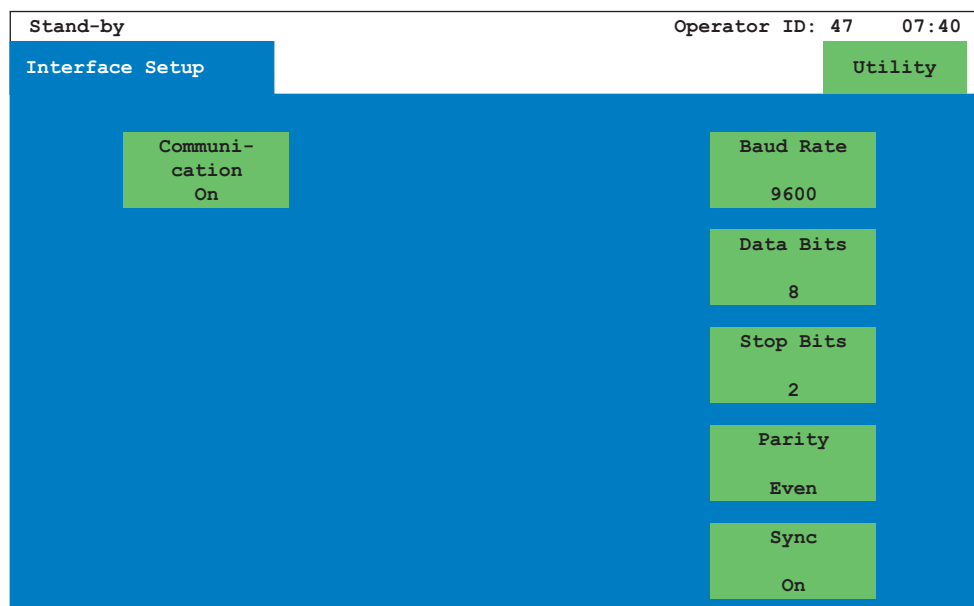
Window Buttons



Initiates the printing of the message history.

7.7 INTERFACE SETUP Screen

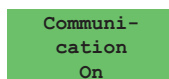
On the **INTERFACE SETUP** screen you can check and set up interface parameters for the host PC. Changes can only be carried out in Stand-by. The communication default setting is **OFF**.



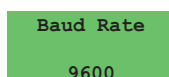
Screen Buttons

Alterations are possible when **Communication Off** is displayed (black text)

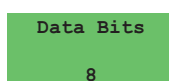
Alterations are not possible when **Communication On** is displayed (white text)



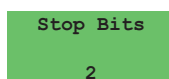
Touching this button accesses the Interface Setup **CONFIRMATION** pop-up window, which allows you to turn communication **ON** or **OFF** (default is **Off**)



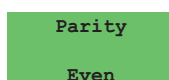
Touch this button until the required baud rate appears. The choices are: 2400, 4800, 9600 and 19200.



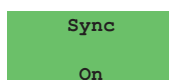
The data bit choices are 7 and 8.



The stop bit choices are 1 and 2.



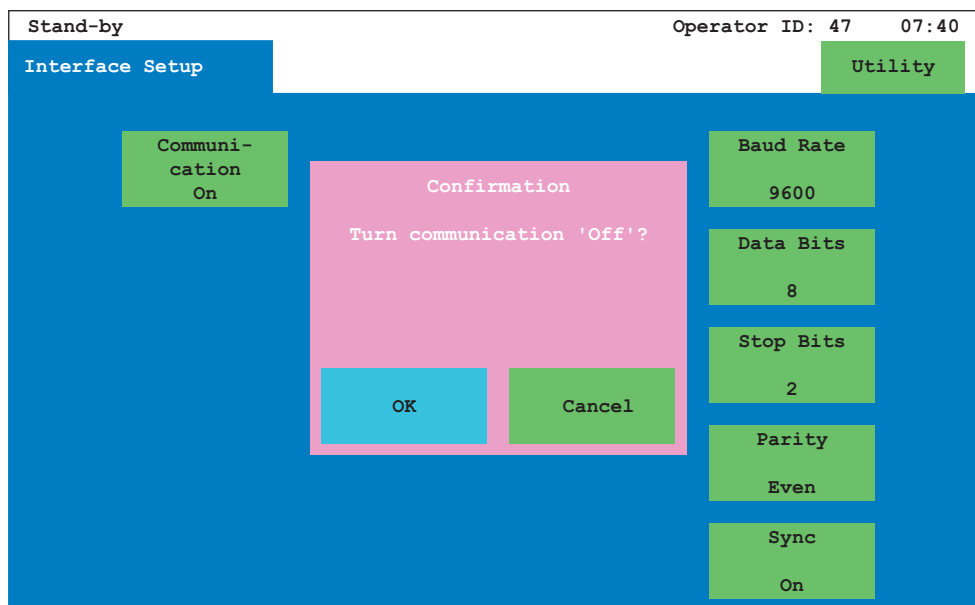
The parity choices are **None**, **Odd** and **Even**.



The synchronization method choices are **On** and **Off**.

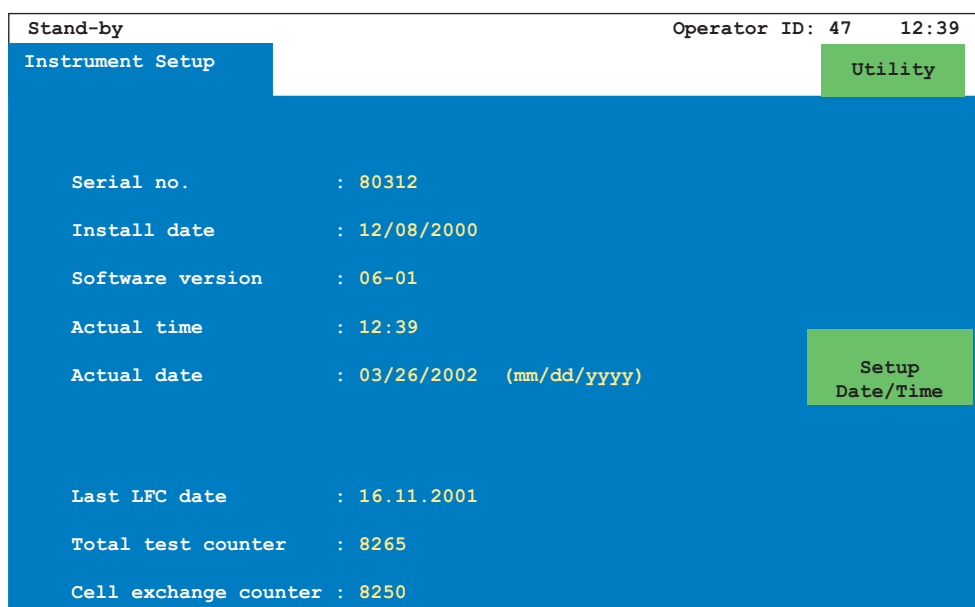
7.7.1 INTERFACE SETUP CONFIRMATION Pop-up Window (Communication)

You can open this window by touching the **COMMUNICATION** button if you wish to enable or disable communication.



7.8 INSTRUMENT SETUP Screen

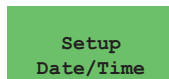
In the **INSTRUMENT SETUP** screen you can check the analyzer information, including the software version, and alter the current date and time.



Display Fields

Analyzer-specific details: **Serial no.**, **Install date** (the date when the software was installed), **Software version**, **Actual time**, **Actual date.**, **Last LFC date** (date of last **L**iquid **F**low **C**leaning). The total cumulative number of tests performed on the analyzer is displayed in the **Total test counter** field. The **Cell exchange counter** field tracks the number of assays performed on the current measuring cell. Both these counters can only be reset to 0 by a service engineer.

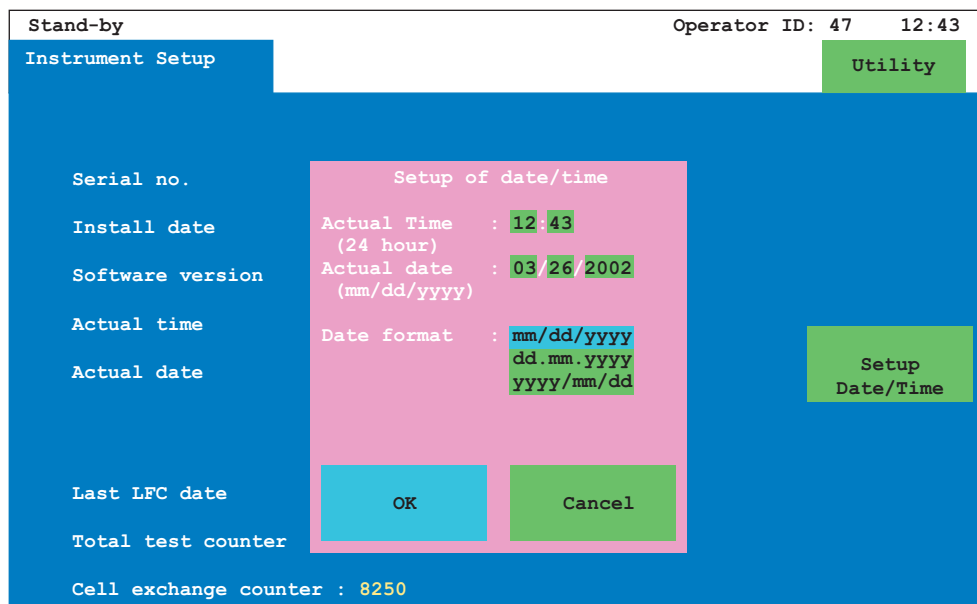
Screen Buttons



Opens the **SETUP DATE/TIME** pop-up window. The date reporting format can also be set here.

7.8.1 SETUP OF DATE/TIME Pop-up Window

This pop-up window is opened by touching the **SETUP DATE/TIME** button. You can set the actual time and date, as well as select the date reporting format you wish to use.



Display and Entry Fields

Actual Time (24 hour)

Display and entry for the time. Touch the field and type the hours and minutes in a 24-hour format.

Actual date (mm/dd/yyyy)

Display and entry for the date. Touch each field and type the month, day and year in the chosen date format.

Date format

Display and choice for the date format. Choose between **mm/dd/yyyy**, **dd.mm.yyyy** or **yyyy/mm/dd**. The chosen format appears as black text on a blue background.

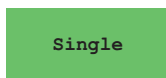
7.9 SAMPLE DISK MODE SETUP Screen



Here you can select the disk mode in which you want to operate your analyzer. This choice can only be made when the analyzer is in Stand-by.



Screen Buttons



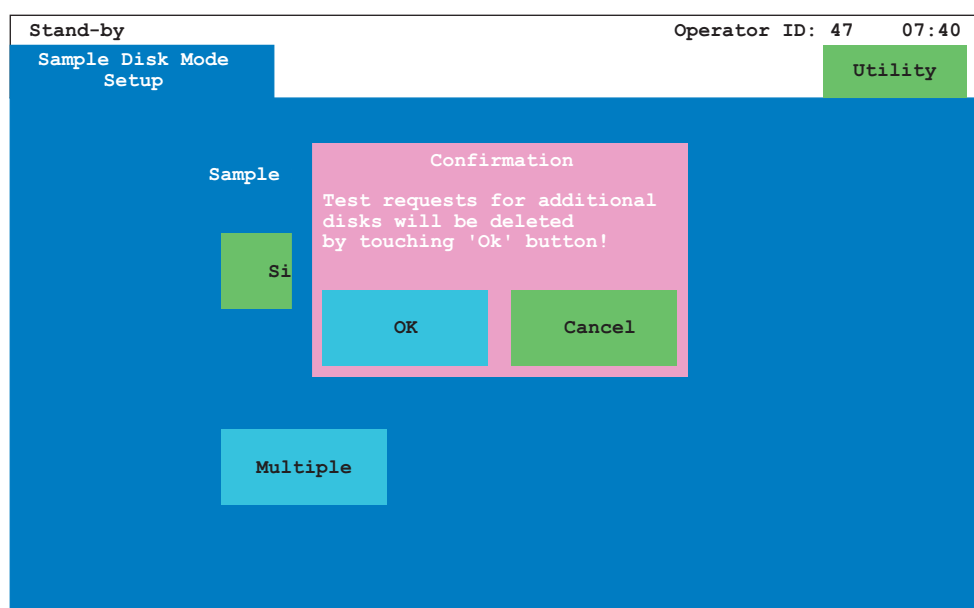
Use this button to select the single sample disk mode. Touching this button accesses the **CONFIRMATION (SAMPLE DISK MODE SETUP)** pop-up window.



Use this button to select the multiple sample disk mode. Touching this button accesses the **CONFIRMATION (SAMPLE DISK MODE SETUP)** pop-up window.

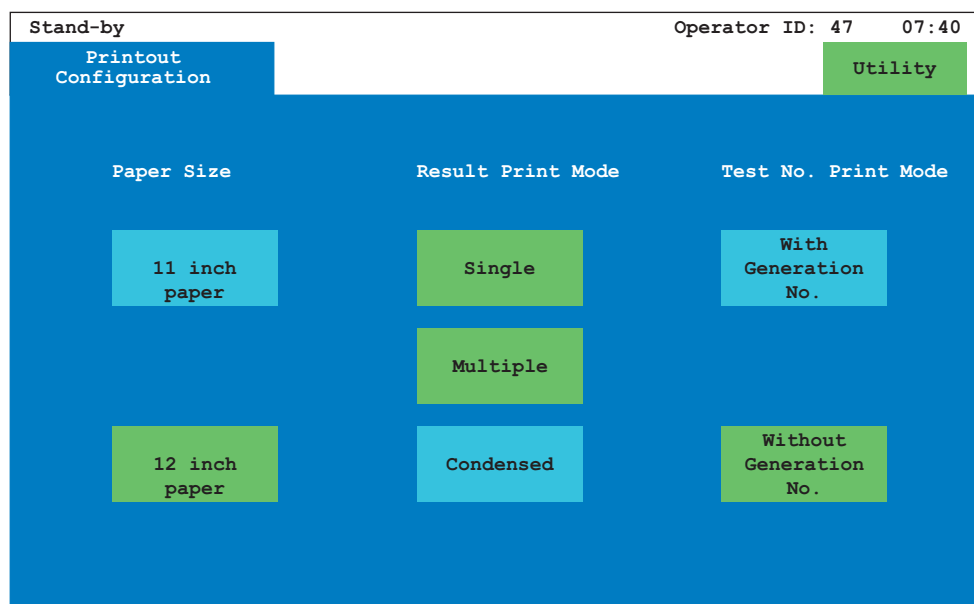
7.9.1 CONFIRMATION Pop-up Window (SAMPLE DISK MODE SETUP)

This pop-up window opens when you touch either the **SINGLE** or **MULTIPLE** button. This window verifies that you want to switch disk modes and informs you that all orders on additional disks will be deleted when working in single mode.



7.10 PRINTOUT CONFIGURATION Screen

Here you can select the format of the results printout, the paper size used and whether the test generation is to appear on the printouts. Changes can only be made in Stand-by.



Display Fields

The choices are grouped together as follows: **Paper Size**, **Results Print Mode** (format) and **Test No. Print Mode** (test generation).

Screen Buttons

A light blue rectangular button with the text "11 inch paper" in a monospaced font.

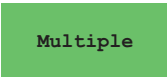
11 inch paper. The button changes color to light blue on selection.

A green rectangular button with the text "12 inch paper" in a monospaced font.

12 inch paper. The button changes color to light blue on selection.

A green rectangular button with the text "Single" in a monospaced font.

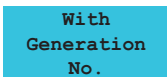
Use to select a single patient report per page. The button changes color to light blue on selection.

A green rectangular button with the text "Multiple" in a monospaced font.

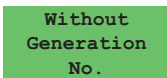
Prints multiple patient reports per page. The button changes color to light blue on selection.

A light blue rectangular button with the text "Condensed" in a monospaced font.

Prints multiple patient reports per page in condensed form. The button changes color to light blue on selection.

A light blue rectangular button with the text "With Generation No." in a monospaced font.

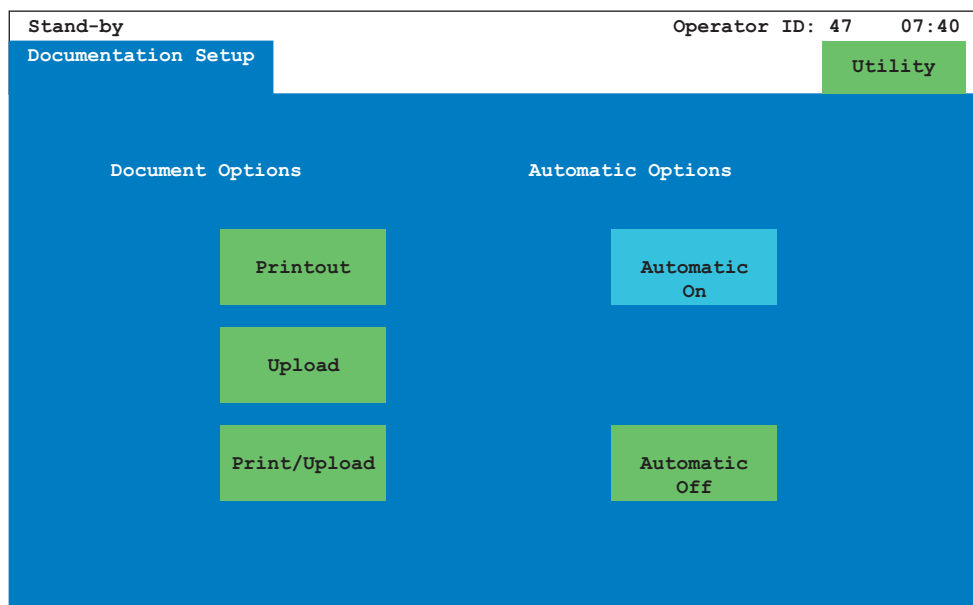
All tests will be printed out with the corresponding generation number. The button changes color to light blue on selection.

A green rectangular button with the text "Without Generation No." in a monospaced font.

All tests will be printed out without the corresponding generation number. The button changes color to light blue on selection.

7.11 DOCUMENTATION SETUP Screen

Here you can set the printout and upload options for the documentation. Changes can only be made in Stand-by.

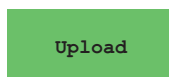


Display Fields

In **Document options**, you can choose the type of documentation you require. Under **Automatic options**, you can turn the automatic documentation **On** or **Off**.



The samples are documented by printing. The button changes color to light blue on selection.



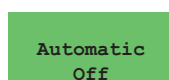
The samples are documented via an upload to the host PC. The button changes color to light blue on selection.



The samples are documented by a combination of printing and uploading. The button changes color to light blue on selection.



The results will be documented automatically in accordance with the **Printout**, **Upload** or **Printout and Upload** selections.



The results must be manually documented in the **RESULTS** screen.



For further information on documenting results, please refer to Chapter 2 in the Tutorial Guide and Chapter 4 in the Software Guide.

7.12 INITIAL BLANKCELL Screen

This screen is reserved for Roche Diagnostics service personnel. It is used at analyzer installation and for service work to the measuring cell. There is no need to use this screen unless specifically directed to do so by Roche Diagnostics Service or Technical Support.

Stand-by		Operator ID: 47		07:40	
Initial BlankCell				Utility	
Initial BlankCell Data				BlankCell Options	
BlankCell procedure date	:	09/03/02		Initial On	
BlankCell reagent pack number	:	415			
BlankCell lot no.	:	93			
BlankCell parameter(a)	:	65			
(b)	:	1.05		Initial Off	

7.13 KEEP FUNCTION SETUP Screen

This screen allows you to define "Keep" functions.

Stand-by		Operator ID: 47		07:40	
Keep Function Setup				Utility	
Keep sample type	:	On	Off		
Default sample type	:	Normal			
Keep test selection	:	On	Off		

Entry Fields**Keep sample type**

If the default selection **On** remains in the **ORDERS** screen, you keep the previously selected sample type (**Normal** or **Reduced**) for patient samples without having to make a renewed selection.

Default sample type

Here you can choose the default sample type, **Normal** (default selection) or **Reduced**. The selection made is displayed in the **ORDERS** screen.

Keep test selection

When set to **On** (default selection), this field allows you to keep sample test selections from order to order. For example, if you request T4 and TSH on a sample, after registering the sample, the next order automatically has T4 and TSH requested for it. If a third assay is selected on this sample, then subsequent samples automatically have three assays requested, and so on.

7.14 MAINTENANCE Screen

In the **MAINTENANCE** screen you can select various maintenance activities. Many functions in this screen are reserved for Roche technical Service.



Stand-by

Operator ID: 4707:40

Maintenance

Utility

System Reset

M. Cell Preparation

M. Cell Exchange

Cleaning

Disinfection

Sipper Pip. Prime

S/R Pipettor Prime

Liquid Flow Cleaning

Finalization Maintenance

FDD Cleaning

FD Write



Stand-by

Operator ID: 4707:40

Maintenance

Utility

System Reset

M. Cell Preparation

M. Cell Exchange

Cleaning

Disinfection

Sipper Pip. Prime

S/R Pipettor Prime

Liquid Flow Cleaning

L. and A. Reset All

Rack Clear

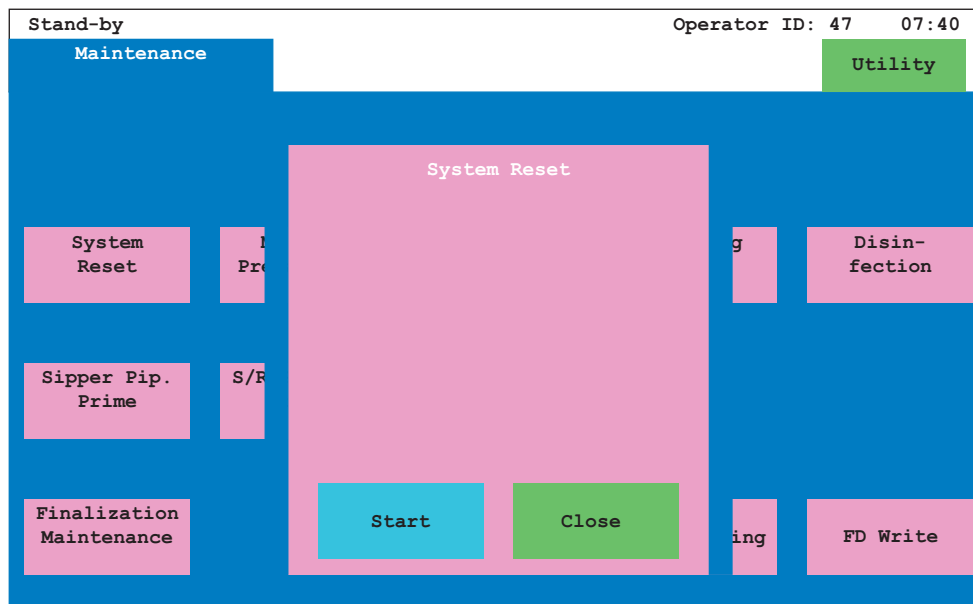
Finalization Maintenance

FDD Cleaning

FD Write

7.14.1 SYSTEM RESET Pop-up Window

This window is opened by touching the **SYSTEM RESET** button in the **MAINTENANCE** screen. When initiating an analyzer system reset, all analyzer mechanisms are returned to their home or Stand-by positions. A system reset is often necessary if the analyzer is in a P. Stop or Stop status due to an alarm condition. This button does not cause a reset of any of the line mechanisms on a rack system.



Window Buttons



Initiates a system reset.

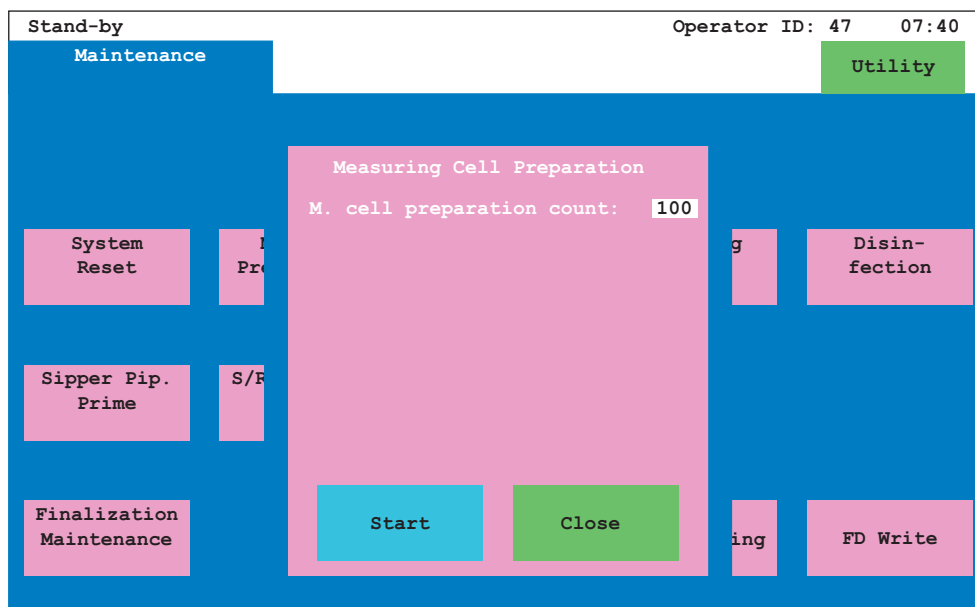
7.14.2 MEASURING CELL PREPARATION Pop-up Window

You can open this window by touching the **M. CELL PREPARATION** button in the **MAINTENANCE** screen. It is used to prime the measuring cell with ProCell.



Caution

Do not use this function for any other purpose unless advised by Roche Diagnostics Service or Technical Support.



Display and Entry Fields

M. Cell preparation count

Display and entry of the number of priming cycles (001 to 100). The default is 100 cycles. If this window is closed, the number of selected priming cycles is displayed on the **M. CELL PREPARATION** button on the **MAINTENANCE** screen. The number counts down until the last cycle is completed.

Window Buttons



Touch this button to initiate the desired priming cycles.

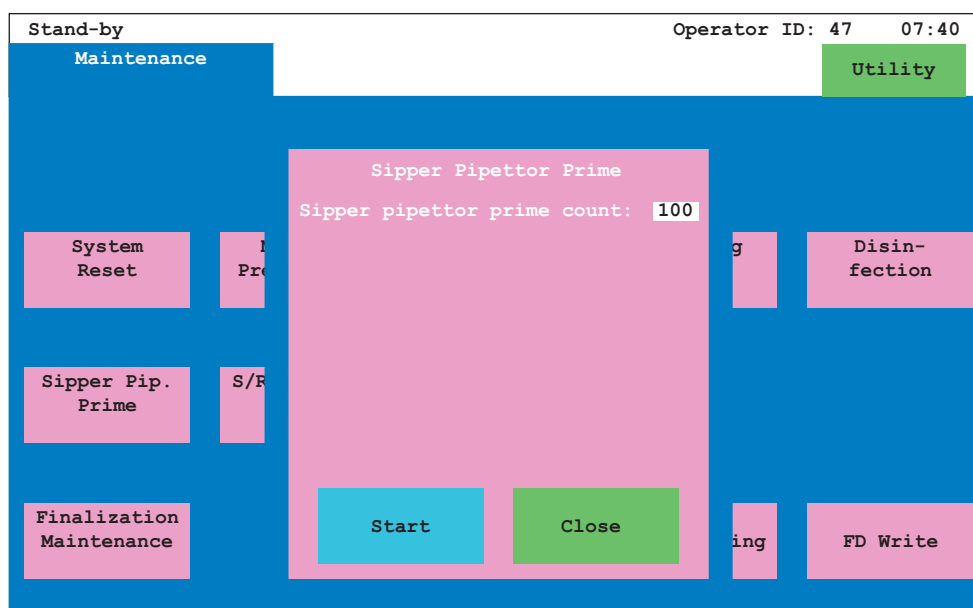
Special Key Functions



Stops the priming function.

7.14.3 SIPPER PIPETTOR PRIME Pop-up Window

This window is opened by touching the **SIPPER PIPETTOR PRIME** button in the **MAINTENANCE** screen. Here you can initiate a priming function of the S/R pipettor with system water. This is necessary after changing pipettor seals.



Display and Entry Fields

Sipper pipettor prime count:

Display and entry of the priming cycles (001 to 100). The default is 100 cycles. If this window is closed, the number of selected priming cycles is displayed on the **SIPPER PIPETTOR PRIME** button in the **MAINTENANCE** screen. The number counts down until the last cycle is completed.

Window Buttons



Touch this button to initiate the desired priming cycles. A number equal to the selected priming cycles is displayed in the **SIPPER PIPETTOR PRIME** button on the **MAINTENANCE** screen.

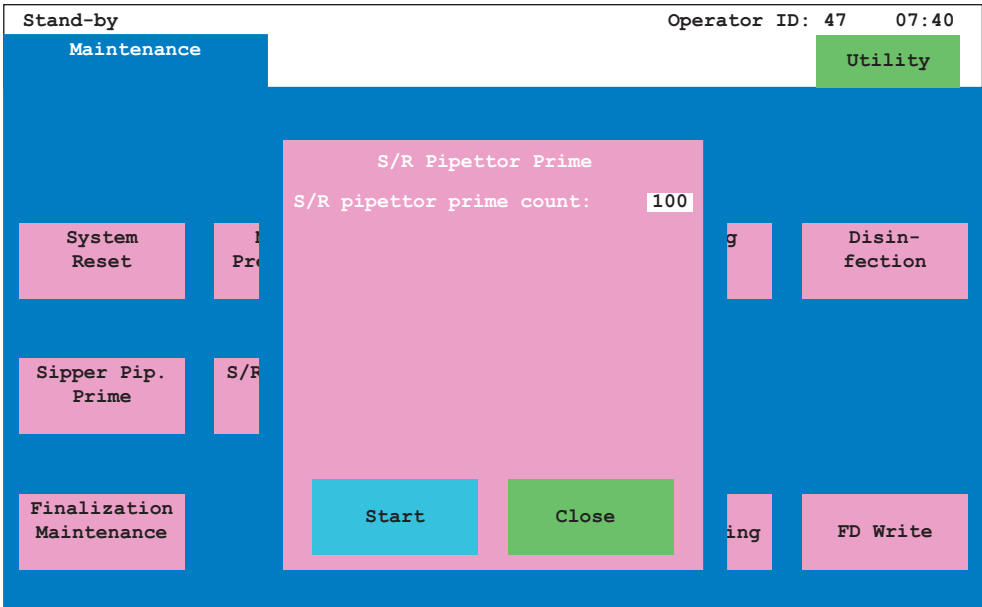
Special Key Functions



Stops the priming function.

7.14.4 S/R PIPETTOR PRIME Pop-up Window

This window is opened by touching the **S/R PIPETTOR PRIME** button. It is used to initiate a priming function of the S/R pipettor with system water. This is necessary after changing pipettor seals.



Display and Entry Fields

S/R pipettor prime count

Display and entry of priming cycles (001 to 100). The default is 100 cycles. This number counts down until the last cycle is completed.

Window Buttons



Touch this button to initiate the desired priming cycles.

Special Key Functions



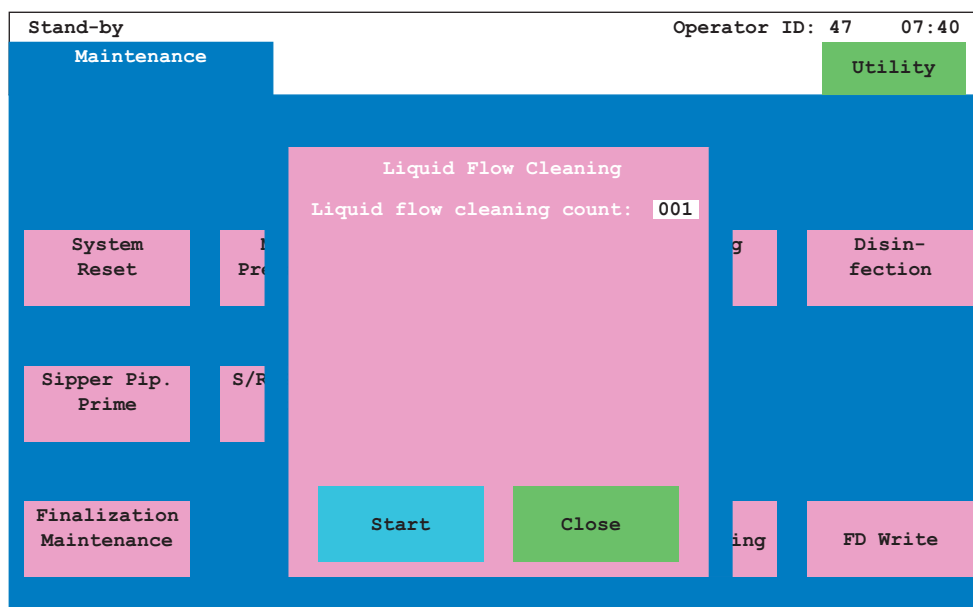
Stops the priming function.

7.14.5 LIQUID FLOW CLEANING Pop-up Window

This pop-up window is opened by touching the **LIQUID FLOW CLEANING** button on the **MAINTENANCE** screen. It is used to initiate the liquid flow cleaning procedure with the SysClean solution. For detailed instructions on the Liquid Flow Cleaning procedure, please refer to Chapter 4, Perform Liquid Flow Cleaning in the User's Guide.



Perform this maintenance procedure every 2 weeks.



Display and Entry Fields

Liquid flow cleaning count

Display and entry of the cleaning cycles (001 to 003). The default is 1 cycle. This number counts down until the last cycle is completed.

Window Buttons



Initiates the desired cleaning cycle. The **CLEANING** button on the **MAINTENANCE** screen displays a number equal to the selected cleaning cycles.

Special Key Functions




Stops the cleaning function.

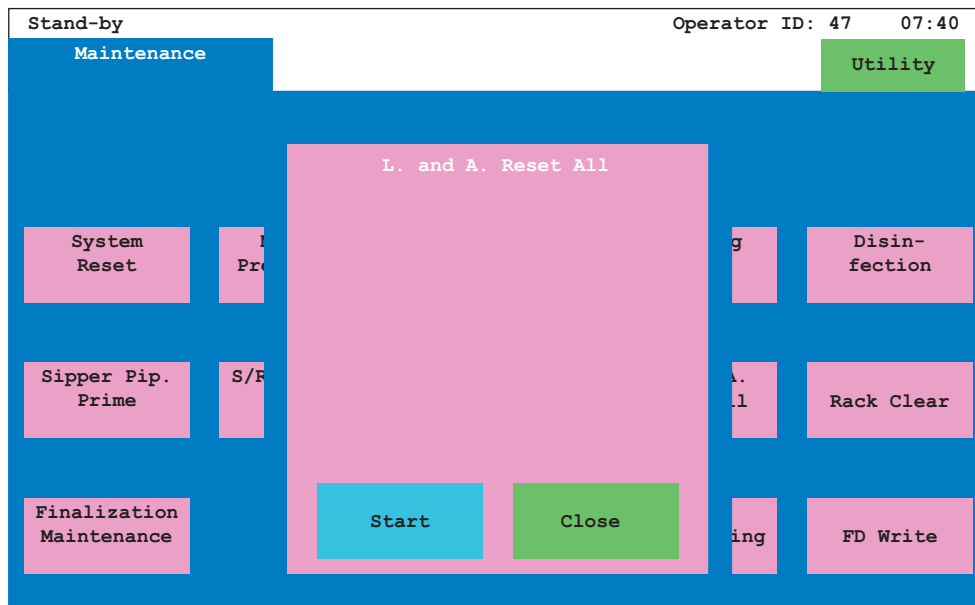


Caution

If you stop the procedure before it is completed, you must restart the procedure or initiate an **M. CELL PREPARATION** function to flush the SysClean solution from the measuring cell.

7.14.6 L. AND A. RESET ALL Pop-up Window

 This pop-up window is opened by touching the **L. AND A. RESET ALL** button on the **MAINTENANCE** screen. It initiates a complete system and line reset for the rack analyzer. A-, B- and C-Lines, as well as returning all analyzer mechanisms to their home or Stand-by positions. An **L. and A. Reset All** is often necessary if the analyzer is in a P. Stop or Stop status due to an alarm condition.




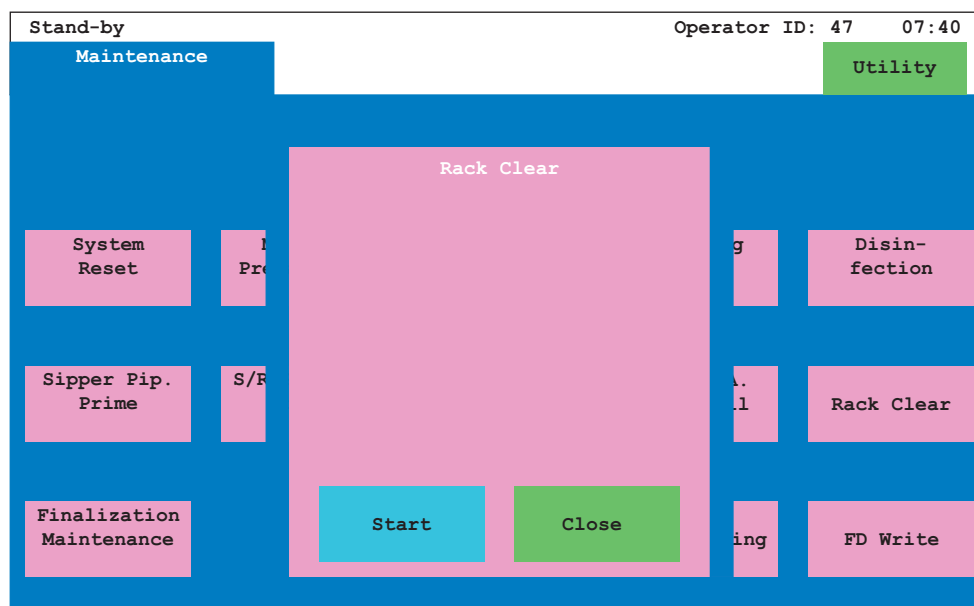
Window Buttons



Starts the **L. and A. Reset All** function.

7.14.7 RACK CLEAR Pop-up Window

 This pop-up window is opened by touching the **RACK CLEAR** button on the **MAINTENANCE** screen. It clears the B-Line of any racks and transfers them to the C-Line.



Window Buttons



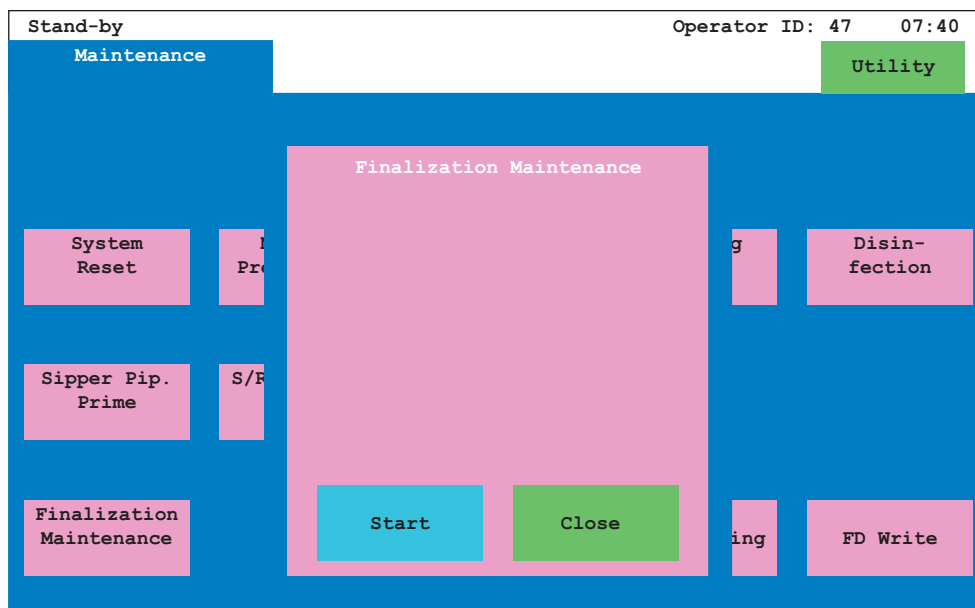
Starts the **Rack Clear** function.

7.14.8 FINALIZATION MAINTENANCE Pop-up Window

This pop-up window is opened by touching the **FINALIZATION MAINTENANCE** button on the **MAINTENANCE** screen. Once the finalization maintenance procedure is started, the system and the sipper probe are primed with water and the measuring cell is filled with ProCell.

This function is initiated automatically by the analyzer approximately thirty minutes after documentation (printout/upload) of the last result. The pump of the pipettor rinse station is activated every 30 minutes for 2 seconds. The system water consumption is 12 mL per priming or about 1 L per weekend.

Exception: The procedure is abandoned by pressing **STOP** or interrupted by switching off the operation switch. The finalization maintenance procedure must be carried out at least once a day (started automatically or manually from the same pop-up window).



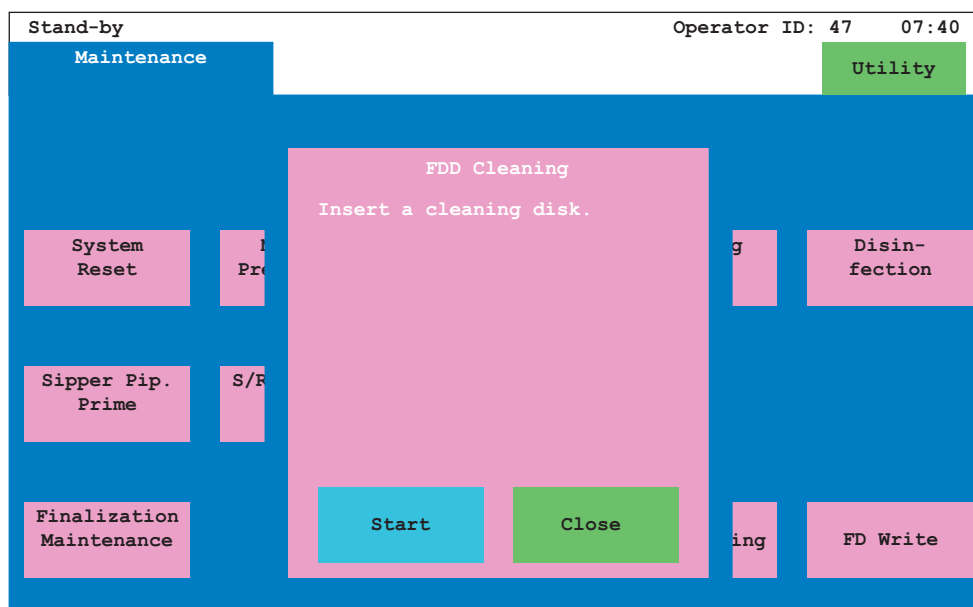
Window Buttons



Starts the **Finalization Maintenance** procedure.

7.14.9 FDD CLEANING Pop-up Window

This pop-up window is opened by touching the **FDD CLEANING** button on the **MAINTENANCE** screen. It is used to clean the floppy disk drive and is recommended once a month.



Window Buttons



Starts the cleaning of the disk drive.



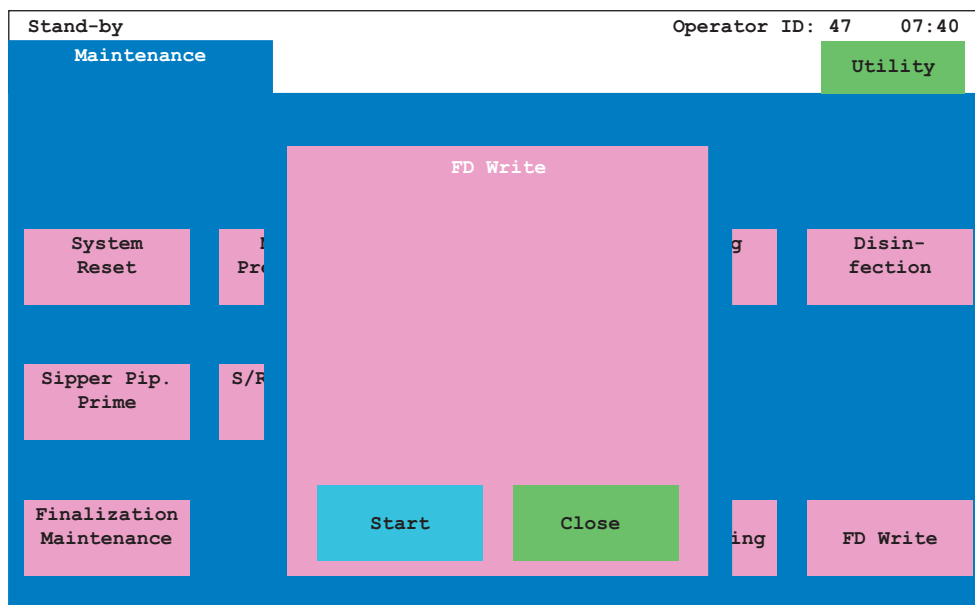
Caution

Verify that the drive is not active (green light is on) before you remove the data disk.

Do not mistakenly place the data disk in the disk drive instead of the cleaning disk! Failure to replace the data disk with the cleaning disk will result in the loss of all data on the data disk! Nevertheless, should data have been lost, place a formatted disk in the drive and initiate the save data function (FD Write), see next section.

7.14.10 FD WRITE Pop-up Window

This pop-up window is opened by touching the **FD WRITE** button on the **MAINTENANCE** screen. It is used to write all data files currently stored in the analyzer memory onto a PC-formatted data disk.



Window Buttons



Starts the copy function for copying files stored in the analyzer memory onto a PC-formatted disk.

7.14.11 Maintenance Windows for Service Personnel

The following pop-up windows are reserved for service personnel:

- M. Cell Exchange Flushes and drains the measuring cell flow path.
- Disinfection Washes the measuring cell flow path.
- Cleaning Cleans the sipper system flow path.

DO NOT perform these functions unless advised by Roche Diagnostics Service.

7.15 TEMPERATURE MONITOR Screen

This screen is used to check temperatures of the temperature controlled units on the analyzer.

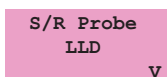
Stand-by		Operator ID: 47 07:40			
Temperatur Monitor		Utility			
		Ambient Temp.	Temperature	Target Temp.	Control Param.
-----		-----			
Detection Unit	:	-----	27.3	27.3	-0.2
Incubator	:	-----	37.0	37.0	1.7
Reagent	:	23.4	18.2	17.7	-0.9
PC/CC	:	26.1	27.8	28.0	0.3
Unit: Degrees Centigrade					

7.16 VOLTAGE MONITOR Screen

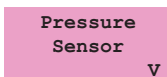
In this screen you can check the LLD voltages of the S/R probe, the pressure sensor for clot detection and the sipper probe. Voltages can only be checked while the analyzer is in Stand-by.

Stand-by		Operator ID: 47 07:40	
Voltage Monitor		Utility	
S/R Probe LLD V	Pressure Sensor V	Sipper LLD V	
1: Touch the button for which you want to display the voltage 2: To see another voltage, touch the Monitoring Stop button. 3: To exit the Voltage Monitor screen, touch the Monitoring Stop button and then the Utility button.			
			Monitoring Stop

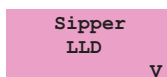
Screen Buttons



This function checks the LLD voltage of the S/R probe. When active, the text on the button changes from black to white and displays the current voltage to the left of the V. Please refer to Chapter 3, Instrument Alarms in the User's Guide, for the recommended voltage.



This function checks the clot detection voltage of the S/R probe. When active, the text on the button changes from black to white and displays the current voltage to the left of the V. Please refer to Chapter 3, Instrument Alarms in the User's Guide, for the recommended voltage.



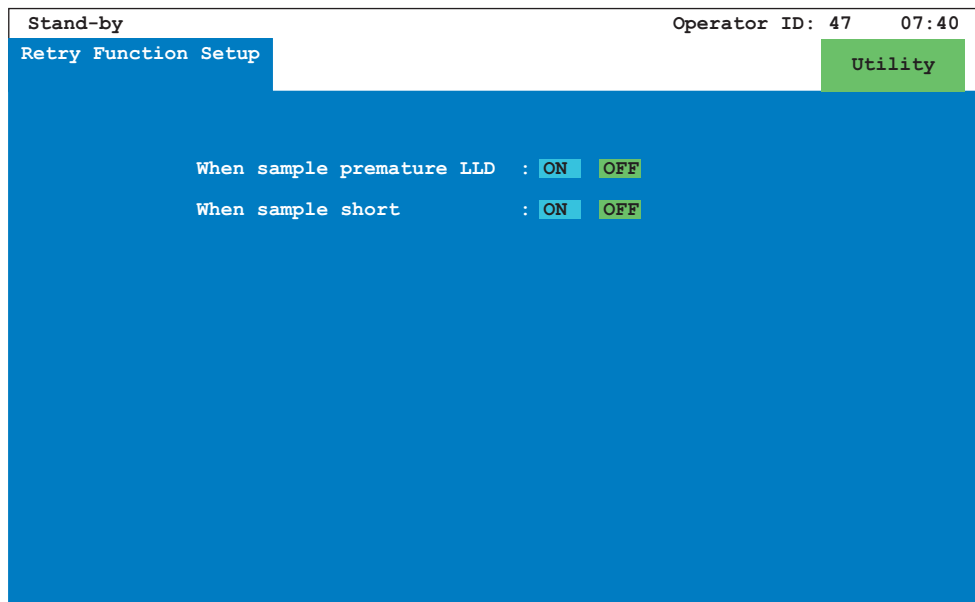
This function checks the LLD voltage of the sipper probe. When active, the text on the button changes from black to white and displays the current voltage to the left of the V. Please refer to Chapter 3, Instrument Alarms in the User's Guide, for the recommended voltage.



Stops monitoring the voltage. When voltages are being monitored, the text on the button is black.

7.17 RETRY FUNCTION SETUP Screen

In this screen the user can request additional sample pipetting procedures if special alarms were issued during the first sample pipetting.



Entry Fields

When sample premature LLD

When this function is set (**ON** is activated), and if one of the following alarms occurs:

“Sample LLD noise (before aspirating) 35-04-02”

“Sample LLD noise (after aspiration) 35-04-03”

the system repeats the pipetting procedure, twice at most, from the same sample cup (no change to “sample cup reduced”).

When sample short

When this function is set (**ON** is activated), and if one of the following alarms occurs:

“Sample short (no LLD before Z-max) 35-03-01”

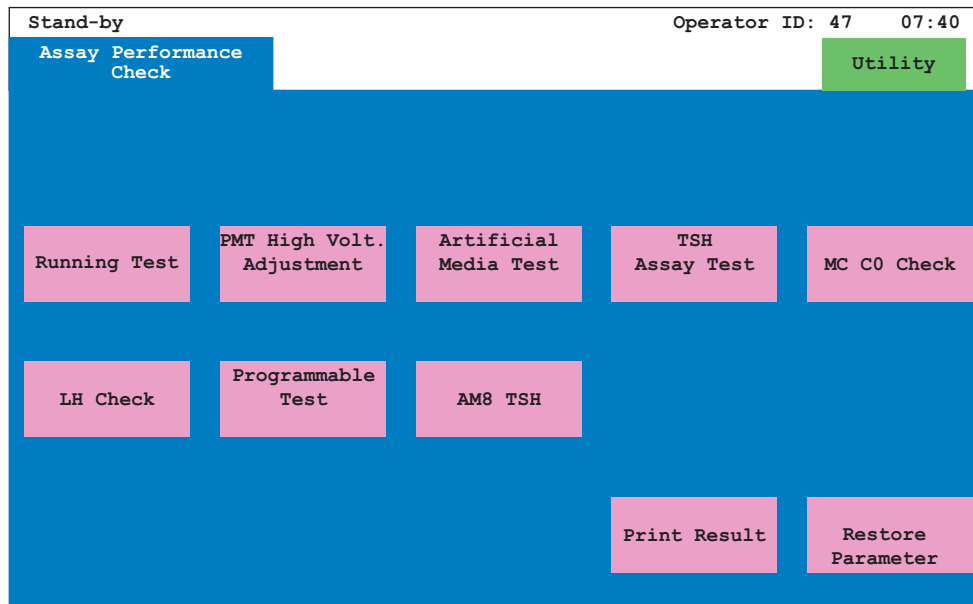
“Sample short (before aspiration) 35-04-01”

the system repeats the pipetting procedure, once only, in the mode “Other” from the same sample cup.

For “sample short” this function works only when the mode is “sample cup normal”. If an LLD is detected, but not within the correct parameters, the instrument changes to the mode “sample cup reduced” and performs a second sample pipetting procedure.

7.18 ASSAY PERFORMANCE CHECK Screen

This screen is reserved for use by Roche Diagnostics service personnel. It is used to perform various service checks on the analyzer. Use this screen only when specifically directed to do so by Roche Diagnostics Service or Technical Support.



7.19 AUTOMATIC ADJUSTMENT Screen

This screen is reserved for use by Roche Diagnostics service personnel. It is used to perform automatic adjustment for the components on the analyzer.

Stand-by		Operator ID: 47			07:40
Automatic Adjustment					Utility
Gripper-X/Y TM Front X:15 Y3	Gripper-X/Y TM Back X:9	Gripper-X/Y CM Left Y6	Gripper-X/Y Sipping X:12 Y4	Gripper-X/Y Incubator Y3	
Gripper-X/Y Tip Pos. 1 X:6 Y5	Gripper-X/Y CB Pos. X:5 Y4	<p>Red Button: Failure to adjust automatically. Try again, after confirming cups/tips.</p> <p>Yellow Button: The position was on mechanical limits. Adjust it manually.</p>			
Gripper-Z Sipping Z5	Gripper-Z CB Pos. Z9				
Gripper All Positions Preparation				Gripper Adjust Data FD Write	Gripper Adjust Data Printout
Gripper All Positions	Magazine Cup/Tip	Sipping Incubator	C/T-Buffer	Gripper-Z	



Caution

DO NOT attempt to use this screen unless specifically directed to do so by Roche Diagnostics Service or Technical Support. Misuse of this screen causes movement errors!

7.20 MECHANISM CHECK Screen

The MECHANISM CHECK screen is reserved for use by Roche Diagnostics service personnel. It is used to check the movements or actions of certain components of the analyzer.



Caution

DO NOT attempt any check unless specifically instructed by Roche Diagnostics Service or Technical Support, because certain instructions, cup/tip placements, etc., are specific to each check.

Do not use this screen unless specifically directed to do so by Roche Service or Technical Support.



Stand-by		Operator ID: 47		07:40	
Mechanism Check			Utility		
Cap Open/Close Check	Mixing Check	Magnet Up/Down	Waste Tray Shaking	Sample BC Scanning	
Bar Code Card Reading	Reagent Pack BC Scanning	Gripper Quick Check	Gripper Rep. Check	S/R Probe Check	
Gripper S/R Probe	Sipper Check	S/R Probe LLD Check			



Stand-by		Operator ID: 47		07:40	
Mechanism Check			Utility		
Cap Open/Close Check	Mixing Check	Magnet Up/Down	Waste Tray Shaking		
Bar Code Card Reading	Reagent Pack BC Scanning	Gripper Quick Check	Gripper Rep. Check	S/R Probe Check	
Gripper S/R Probe	Sipper Check	S/R Probe LLD Check			
Sampler Check					

7.21 SERVICE Screen

This password-protected screen is reserved for use by Roche Diagnostics service personnel.

The screenshot displays the SERVICE screen interface. At the top, a status bar shows "Stand-by" on the left, "Operator ID: 47" in the center, and "07:40" on the right. Below this, a blue header bar contains the word "Service" on the left and a green button labeled "Utility" on the right. The main area of the screen is blue. In the center, a pink rectangular dialog box is displayed. Inside this dialog, the text "Password ?" is followed by a white input field. Below the input field are two buttons: a cyan button labeled "OK" and a green button labeled "Cancel".

8. Reports

8.1 Overview of Options

The reports and lists in the table below can be printed out. With the exception of the **TEST RESULTS** printout and the **MESSAGE HISTORY** printout all printouts are initiated by pressing the **DOC** key when in the appropriate screen.

Report Name (Printout)	Request from this screen or pop-up window
Inventory	INVENTORY
Work List	ORDERS
Results	RESULTS or DOCUMENT SETUP pop-up window
QC Results	QC
Status	STATUS
Control Definition	CONTROL DEFINITION (UTILITY folder)
Calibration Data	CALIBRATION DATA or CALIBRATION DATA DETAILS pop-up window (UTILITY folder)
Test Conditions	TEST CONDITIONS or TEST CONDITIONS DETAILS pop-up window
Message History	PRINT MESSAGE HISTORY (UTILITY folder)

8.2 INVENTORY Report

This list offers an overview of the reagent packs, cups, tips and other consumables currently on the analyzer.

Inventory		Operator ID: 10		02/27/2002 13:40	

Disk Pos.	Test Code	Test No.	Lot No.	Tests Left	MCR/MQR

2	T-UP	4	192952	172	
3	FT4	3	193472	173	C
4	FT3	6	193370	174	
5	T4	2	190764	163	
6	T3	5	192875	164	
7	TNTSTAT	20	193592	60	
8	CKMBSTAT	21	192915	61	
9	HCGSTAT	17	193367	54	
12	TSH	1	192951	35	
15	TSH	1	192951	200	CR
17	Dil Uni	0	192999	16	
Assay cups	:	27			
Assay tips	:	58			
System reagent	Set 1 :	67 %			
	Set 2 :	56 %			
PC lot no.	Set 1 :	123456			
	Set 2 :	254136			

Explanation of the Inventory Report**Disk Pos.**

The reagent disk position of the reagent pack. The report is sorted by disk position number.

Test Code

The test abbreviation assigned to the assay.

Test No.

The designated test number of the assay. This number is encoded in the reagent bar code, but can be changed in the **TEST CONDITIONS DETAILS** pop-up window (**UTILITY** folder).

Lot No.

The lot number of the reagent pack.

Tests Left

The number of tests remaining in the reagent pack.

MCR/MQR

A **CR** or **C** appears in this field if a calibration is required or manually requested for the reagent pack. A corresponding **CR** or **C** appears on the appropriate test button in the **INVENTORY** screen. A **M** appears in this field if a quality control is requested manually for the reagent pack.

Assay cups

The number of cups remaining.

Assay tips

The number of tips remaining.

System reagent, Set 1, Set 2

The percentage of ProCell and CleanCell remaining in each bottle set is listed here.

PC lot no.

The lot number of ProCell in use in each bottle set. This number is entered in the **SYSTEM REAGENT DETAILS** pop-up window (**INVENTORY** screen).

8.3 Work List



Work Lists of the calibrators, controls and samples currently loaded on the sample disk, as well as the tests selected. This list also contains test selections downloaded from the host for assays not currently loaded on the analyzer.



Work Lists of the calibrators, controls and samples (and their test selections) currently loaded on the sample racks. This list also contains test selections downloaded from the host for assays not currently loaded on the analyzer.



Work List					
			Operator ID: 10		02/27/2002 13:40
ID	Pos.	Seq.	Vol.	Type	Selected Tests
Cal 1	0-	1	11	15 Calibrator	FT4
Cal 2	0-	2	12	15 Calibrator	FT4
Cal 1	0-	3	13	50 Calibrator	TSH
Cal 2	0-	4	14	50 Calibrator	TSH
Cal 1	0-	5	15	15 Calibrator	T4
Cal 2	0-	6	16	15 Calibrator	T4
PC U1	0-	7	17	80 Control	FT4,TSH,T4
PC U2	0-	8	18	80 Control	FT4,TSH,T4
00449	0-	9	19	15 Sample	FT4
000024	0-	10	20	65 Sample	TSH (D=10) ,T4
004893	0-	11	21	80 Sample	FT4,TSH,T4
003822	0-	12	22	80 Sample	FT4,TSH,T4
003828	0-	13	24	80 Sample	FT4,TSH,T4
002955	0-	14	25	30 Sample	TNTSTAT,CKMBSTAT
002884	0-	15	26	30 Sample	TNTSTAT,CKMBSTAT
Rgt packs required : TSH ,FT4 ,T4 ,TNTSTAT ,CKMBSTAT					
Tips required : 70					
Cups required : 34					



Work List					
			Operator ID: 10		02/27/2002 13:40
ID	Rack-Pos.	Seq.	Vol.	Type	Selected Tests
00449	00022 - 1	19	15	Sample	FT4
000024	00022 - 2	20	65	Sample	TSH (D=10) ,T4
004893	00022 - 3	21	80	Sample	FT4,TSH,T4
003822	00022 - 4	22	80	Sample	FT4,TSH,T4
003828	00022 - 5	24	80	Sample	FT4,TSH,T4
002955	00023 - 1	25	30	Sample	TNTSTAT,CKMBSTAT
002884	00023 - 2	26	30	Sample	TNTSTAT,CKMBSTAT

Explanation of the Work List

ID

The identification number or abbreviation of the sample, calibrator or control.



Pos.

The sample disk number and position occupied by the sample.



Rack Pos.

The sample rack ID and position occupied by the sample.

Seq.

The sequence number of the sample, calibrator or control.

Vol.

The amount of sample required (in μL), without the dead volume of the container.

Type

Sample type identifier (Calibrator, Control, Sample or STAT).

Selected Tests

Tests selected for the sample are listed here. If a dilution is requested for an assay, it is also listed here.

**Rgt packs required**

The reagent packs required to perform the requested tests.

**Tips required**

The total number of assay tips required to perform the requested tests.

**Cups required**

The total number of assay cups required to perform the requested tests.

8.4 TEST RESULTS Report

The Test Results report lists all results for a specific sample or samples. This report is identical in appearance to the **RESULTS** report. In the **PRINTOUT CONFIGURATION** pop-up window (**UTILITY** folder) you can decide to have single results per page, multiple results per page or results in condensed form. Results can be printed out automatically if the option is set in the **DOCUMENTATION SETUP (UTILITY folder)**.

- The printout of the results of several tests at once, is initiated in the **DOCUMENT SETUP** pop-up window (**Document** button) on the **RESULTS** screen. First select the sequence range of samples and touch **OK**.
- The printout of the test result for just one sample is initiated by pressing the **DOC** key when in the **RESULTS** screen.

Test Results		Operator ID: 10		02/27/2002 13:40	

Sample ID	: 120018	Seq No.	: 45	Documented	
Disk - Pos.	: 0- 9	Sampling Date	: 02/27/2002 11:29		
Test Code	Result	Unit	Dil.	Exp. Values	Note Ready Flag

T4	NoValue	ug/dl	[5.000- 11.50]	11:47 45S
HCGSTAT	426.46	mIU/ml	[0.00- 5.00]	11:48 49
Flags : 45 = Abnormal aspiration					
49 = Above expected value range					
S = System Block					

One sample per page

Test Results		Operator ID: 10		02/27/2002 13:40	

Sample ID	: 000018	Seq No.	: 44	Documented	
Disk - Pos.	: 0- 8	Sampling Date	: 02/27/2002 11:30		
Test Code	Result	Unit	Dil.	Exp. Values	Note Ready Flag

TSH	< 0.005	uIU/ml	[0.230-	3.80] 11:49 46
Flags : 46 = Potential carryover					
Sample ID	: 120018	Seq No.	: 45	Documented	
Disk - Pos.	: 0- 9	Sampling Date	: 02/27/2002 11:29		
Test Code	Result	Unit	Dil.	Exp. Values	Note Ready Flag

T4	NoValue	ug/dl	[5.000- 11.50]	11:47 45S
HCGSTAT	426.46	mIU/ml	[0.00- 5.00]	11:48 49
Flags : 45 = Abnormal aspiration					
49 = Above expected value range					
S = System Block					
Sample ID	: 120156	Seq No.	: 46	Documented	
Disk - Pos.	: 0- 10	Sampling Date	: 02/27/2002 11:30		
Test Code	Result	Unit	Dil.	Exp. Values	Note Ready Flag

T4	7.52	ug/dl	[5.000- 11.50]	11:46
HCG	211.39	mIU/ml	[0.00- 5.00]	11:47 49
Flags : 49 = Above expected value range					

Multiple samples per page



Test Results		Operator ID	

Sample ID	:	000018	
Disk - Pos.	:	0- 8	
Test Code	Result	Unit	Dil.

TSH	< 0.005	uIU/ml	



Test Results		Operator ID	

Sample ID	:	11007648	
Rack ID - Pos.	:	00003 - 1	
Test Code	Result	Unit	Dil.

B12 0	191.1	pmol/l	
FOL 0	14.33	nmol/l	

Explanation of the Test Results Report

Sample ID

The identification number of the sample.

P

Samples designated as pre-diluted (in other words, manually diluted) in the **ORDERS** screen are noted with a P at the end of the Sample ID field.



Disk – Pos.

Sample disk number and position occupied by the sample.



Rack ID – Pos.

Rack ID number and position occupied by the sample.

Seq No.

The sequence number assigned to the sample.

Documented

This word appears if the sample was previously documented. This word is missing from reports that are documented for the first time.

Sampling Date

The time and date when the sample in question was sampled.

Test Code

The test abbreviation assigned to the assay.

Result

The test result.

Unit

The unit of measure. A primary unit is encoded in the reagent bar code. If available, another unit can be selected in the **TEST CONDITIONS DETAILS** pop-up window (**UTILITY** folder). If you change the unit of measure after results have printed, the software does not recalculate the result based on the new unit.

Dil.

The dilution factor. If no dilution was selected in the **DILUTION FACTOR** pop-up window, this field is empty.

Exp. Value

The expected values for the assay are printed if the **Expected Values Check** feature is **ON**. The **Expected Values Check** is found in the **TEST CONDITIONS DETAILS** pop-up window (**UTILITY** folder). The expected values are encoded in the reagent bar code; however, they can be changed in the **TEST CONDITIONS DETAILS** pop-up window (**UTILITY** folder).

Note

A result message that is displayed if a predefined result condition exists. These messages are set in the software and are not user-definable.

The messages are **reac.**, **n-reac.** and **border**. They are limited to qualitative assays. This note is not sent to the host.

Ready

The time when the sample test results were completed.

Flag

Any flags generated by the system during result measurement. A list of data flags and their descriptions is found in Chapter 2 in the User's Guide.

Printout in the Condensed Mode

The settings for a report in condensed form are made in the **DOCUMENTATION** screen (**UTILITY** folder).

Test Results		Operator ID: 02			02/27/2002 11:54		
Sample/Control ID	Seq.	Pos.	TestCode	Dil	RPos.	Result	Flag
11007648	636	00003-1	B12 0		-	191.1	
			FOL 0		-	14.33	
11007748	637	00007-1	TSH 0		-	97.87	49

Explanation of the Condensed Mode Report

Sample/Control ID

The identification number of the sample or control.

Seq.

The sequence number assigned to the sample or control.

Pos.



Sample disk number and position occupied by the sample.



Rack ID number and position occupied by the sample.

TestCode

The test abbreviation assigned to the assay.

Dil

The dilution factor. If no dilution was selected in the **DILUTION FACTOR** pop-up window, this field is empty.

RPos.

The position of the reagent pack in the reagent rotor.

Result

The test result.

Flag

Any flags generated by the system during result measurement. A list of data flags and their descriptions is found in Chapter 2 in the User's Guide.

8.5 RESULTS Report

The Results report is an automatic real time printout of sample results. It shows all test results for a sample. The report is identical in form and content with the **TEST RESULTS** report. This report is only available if automatic options are selected and document option is printout or print/upload in the **DOCUMENTATION SETUP** screen (**UTILITY** folder).

In the **PRINTOUT CONFIGURATION** screen (**UTILITY** folder) you can determine if single or multiple patient reports per page are to be printed, or if the reports are to be printed in super condensed form.

Test Results		Operator ID: 10		02/27/2002 13:40	

Sample ID : 120018		Seq No. : 4000 Documented			
Rack ID - Pos. : 00005- 5		Sampling Date : 02/27/2002 11:29			
Test Code	Result	Unit	Dil.	Exp. Values	Note Ready Flag

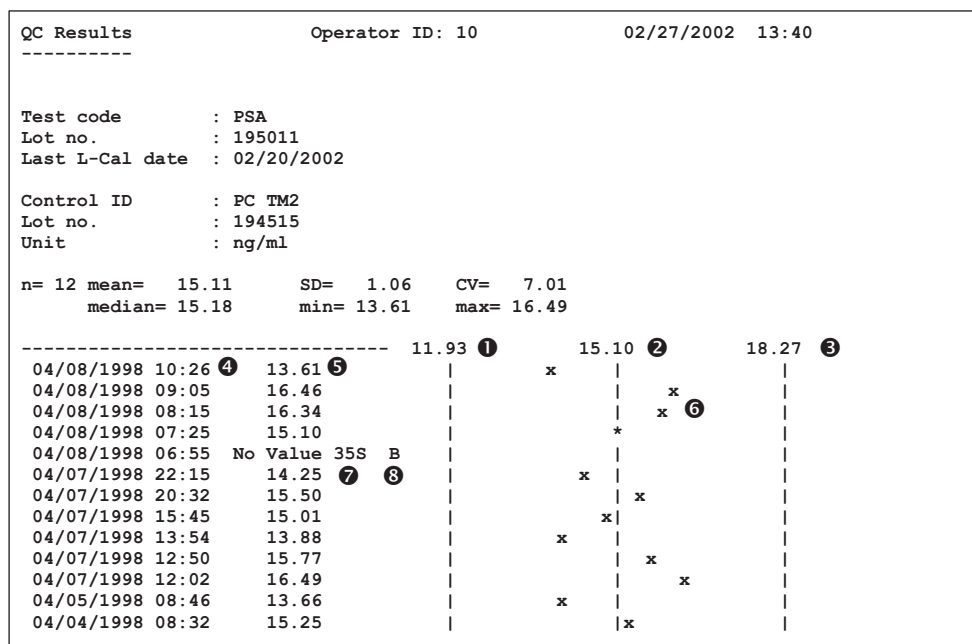
T4	NoValue	ug/dl	[5.000- 11.50]	11:47 45S
HCGSTAT	426.46	mIU/ml	[0.00- 5.00]	11:48 49
Flags : 45 = Abnormal aspiration					
49 = Above expected value range					
S = System Block					



You can find a description of the individual fields in Chapter 8.4

8.6 QC RESULTS Report

The QC Results report provides a list of a test code's control values for the selected control. The concentrations are shown graphically relative to the minimum value, target value and maximum value for the control. Statistics for the control are listed above the graphic representation.



Explanation of the QC Results Report

Test code

The test abbreviation assigned to the selected test.

Lot no.

The lot number of the selected test.

Last L-Cal date

The date of the assay's last valid lot calibration.

Last R-Cal date

The date of the assay's last valid reagent calibration.

Control ID

The control test code.

Lot no.

The lot number of the selected control level.

Unit

The unit of measure for the selected test. The unit of measure is selected in the **TEST CONDITIONS** screen (**UTILITY** folder).

n

The number of control results for the chart (assay/control combination). You need at least five results to generate statistics. Blocked values are not included in the statistics.

mean

The mean value of all control results is indicated.

SD

This field displays the standard deviation.

CV

The coefficient of variation is displayed in this field.

median

The median of the control results is displayed here.

min/max

Displays the minimum and maximum control result of all results on the chart.

- ❶ The lower limit of the control range.
- ❷ The target value of the control.
- ❸ The upper limit of the control range.
- ❹ The date and time the control result was measured.
- ❺ The control result.
- ❻ The control result displayed graphically as an "x". An asterisk indicates that the values falls exactly on the minimum, target or maximum value.
- ❼ Any data flags that occurred at the same time of the control result.
- ❽ If a control result is blocked, a **B** appears here.

8.7 STATUS Report

The Status report provides a list of the current status of all the samples on the sample disk or in racks that have been scanned-in by the bar code reader and processed.



Status					

			Operator ID: 10	02/27/2002 09:56	
ID	Pos.	Seq.	Type	Status	Ready Time

Cal 1	0- 1	11	Calibrator	Active Sample	
Cal 2	0- 2	12	Calibrator	Active Sample	
Cal 1	0- 3	13	Calibrator	Active Sample	
Cal 2	0- 4	14	Calibrator	Active Sample	
Cal 1	0- 5	15	Calibrator	Active Sample	
Cal 2	0- 6	16	Calibrator	Occupied	
PC U1	0- 7	17	Control	Occupied	
PC U2	0- 8	18	Control	Occupied	
00449	0- 9	19	Sample	Occupied	
000024	0-10	20	Sample	Occupied	
004893	0-11	21	Sample	Occupied	
003822	0-12	22	Sample	Occupied	
003828	0-13	24	Sample	Occupied	
002955	0-14	25	Sample	Occupied	
002884	0-15	26	Sample	Occupied	
Empty Positions : 0-16, 0-17, 0-18, 0-19, 0-20, 0-21, 0-22, 0-23, 0-24,					
0-25, 0-26, 0-26, 0-27, 0-28, 0-29, 0-30					



Status					

			Operator ID: 10	02/27/2002 09:56	
ID	Rack-Pos.	Seq.	Type	Status	Ready Time

Cal 1	00012 - 1	4271	Calibrator	Active Sample	
Cal 2	00012 - 2	4272	Calibrator	Occupied	
PC U1	00012 - 3	4273	Control	Occupied	
PC U2	00012 - 4	4274	Control	Occupied	
Cal 1	00011 - 1	4266	Calibrator	Complete	00:00
Cal 2	00011 - 2	4267	Calibrator	Complete	00:00
Cal 1	00011 - 3	4268	Calibrator	Complete	00:00
Cal 2	00011 - 4	4269	Calibrator	Complete	00:00
004499	00010 - 1	4270	Sample	Complete	07:30
000024	00010 - 2	4261	Sample	Complete	07:30
004893	00010 - 3	4262	Sample	Complete	07:31
003822	00010 - 4	4263	Sample	Complete	07:32
003828	00010 - 5	4264	Sample	Complete	07:34
002884	00010 - 1	4265	Sample	Complete	07:23
002955	00010 - 2	4256	Sample	Complete	07:24
003697	00010 - 3	4257	Sample	Complete	07:06
003158	00010 - 4	4258	Sample	Complete	07:25
006897	00010 - 5	4259	Sample	Complete	07:20
005446	00010 - 1	4260	Sample	Complete	07:20
005444	00010 - 2	4253	Sample	Complete	07:21
009687	00010 - 3	4254	Sample	Complete	07:22
002222	00010 - 4	4255	Sample	Complete	07:34

Explanation of the Status Report

ID

The identification number or designation of the sample material (sample, calibrator, control).



Pos.

The current sample disk number and position occupied by the sample.



Rack-Pos.

The current rack ID and position occupied by the sample.

Seq.

The sequence number assigned to the sample.

Type

The sample type identifier. Identifiers are Calibrator, Control, Sample or STAT.

**Status**

Possible statuses are:

In STATUS Report	On the screen
STAT	STAT
Occupied	Occup
Active Sample	Smpl
In Process	Proc
Incomplete	Incmp
Complete	Compl
Stop (Disk only)	Stop

**Ready time**

The time when the sample disk was completed.

**Ready**

The time when the sample rack was completed.

**Empty positions**

A list of positions on the sample disk, that are empty, have not been scanned or ordered.

8.8 CONTROL DEFINITION Report

The report contains a list of all defined tests for a control lot.

Control Definition		Operator ID: 02	02/27/2002 13:34

Control ID	:	PC U1	
Control no.	:	1	
Control lot no.	:	195686	
Exp. date	:	08/2000	
Test no.	:	20	
Test code	:	T4	
Unit	:	nmol/l	
Assay Lot No.	:	Target Value	Target Range
150093	:	98.70	[77.97 - 119.4]
Test no.	:	30	
Test Code	:	Ft4	
Unit	:	pmol/l	
Assay Lot No.	:	Target Value	Target Range
198160	:	16.00	[13.60 - 18.40]
10302	:	16.00	[13.60 - 18.40]
Test no.	:	50	
Test Code	:	T3	
Unit	:	nmol/l	
Assay Lot No.	:	Target Value	Target Range
198180	:	2.24	[1.77 - 2.71]
Test no.	:	60	
Test Code	:	FT3	
Unit	:	pmol/l	
Assay Lot No.	:	Target Value	Target Range
150588	:	5.25	[4.30 - 6.20]
Test no.	:	100	
Test Code	:	E2	
Unit	:	pmol/l	
Assay Lot No.	:	Target Value	Target Range
199871	:	605.6	[333.1 - 878.0]
Test no.	:	110	
Test Code	:	TESTO	
Unit	:	nmol/l	

Control Definition report for a Roche control

Control Definition	Operator ID: 10	02/27/2002 13:46

Control ID	: Control A	
Control no.	: 64	
Control lot no.	: 123456	
Exp. date	: 10/1999	
Test no.	: 1	
Test code	: TSH	
Unit	: uIU/ml	
Target value	: 1.77	
Target range	: [1.77 - 2.07]	
Test no.	: 86	
Test code	: T4	
Unit	: ug/dl	
Target value	: 11.49	
Target range	: [9.29 - 13.69]	
Test no.	: 3	
Test code	: FT4	
Unit	: ng/dl	
Target value	: 2.32	
Target range	: [2.12 - 2.52]	
Test no.	: 17	
Test code	: HCGSTAT	
Unit	: mIU/ml	
Target value	: 9.18	
Target range	: [6.73 - 11.63]	
Test no.	: 31	
Test code	: AFP	
Unit	: IU/ml	
Target value	: 9.93	
Target range	: [7.06 - 10.29]	
Test no.	: 38	
Test code	: FERR	

Control definition report for a non-Roche control

Explanation of the Control Definition Report

Control ID

The control test code.

Control no.

The assigned control number for the control level. Numbers 1 to 63 are reserved for Roche controls and cannot be changed. Numbers 64 to 99 are for non-Roche controls.

Control lot no.

The lot number of the control level.

Exp. date

The expiration date of the control level.

Test no.

The assigned test number for assay selected for the control.

Test code

The test code of the assay selected for the control.

Unit

The unit of measure. A primary unit is encoded in the reagent bar code. If available, another unit can be selected in the **TEST CONDITIONS DETAILS** pop-up window (**UTILITY** folder). If you change the unit of measure after results have printed, the software does not recalculate the result based on the new unit.

Assay Lot No.

The lot number of the measured test.

Target value

The target value for the selected assay for the control level. This value is encoded on the control bar code card or the reagent bar code label. For a non-Roche control or laboratory specific values, this is the value entered in the **CONTROL DEFINITION DETAILS** pop-up window.

Target range

Upper and lower target range of the control for the assay. For a non-Roche control or laboratory specific values, this is the range resulting from the percentage entered in the **CONTROL DEFINITION DETAILS** pop-up window.

8.9 CALIBRATION DATA Report

The Calibration Data report is generated automatically following calibration if automatic options are ON in the **DOCUMENTATION SETUP** screen (**UTILITY** folder). It contains information on the specific reagent pack and L-Cal and R-Cal details. Also included in this report are calibration quality criteria. These criteria are used to determine if the calibration is successful, questionable or failed. The report can be requested manually at any time in the **CALIBRATION** screen (**UTILITY** folder).

Calibration Data		Operator ID: 02	10/02/2002 13:35

Lot calibration was successful			
Test code	:	PSA 1	
Unit	:	ng/ml	
Lot no. reagent pack	:	159109	
Reagent pack number	:	42110	
Exp. date reagent pack	:	05/2003	
Lot Calibration			
Lot calibration date	:	10/02/2002	
Reagent pack no. for Lot Calib.	:	42110	
Lot no. of calibrator	:	159899	
Exp. date calibrator	:	06/2003	
Recommended at	:	11/01/2002	
R. Pack Calibration			
Reagent pack calibration date	:	10/02/2002	
Reagent pack no. for R. pack cal.	:	42110	
Lot no. of calibrator	:	159899	
Exp. date calibrator	:	06/2003	
Recommended at	:	10/09/2002	
Calibration Quality Criteria			
Missing values		-----	
Monotony of curve		-----	
Calibration factor		1.00	
Minimum signal		-----	
Minimum acceptable difference		-----	
Deviation of dup. measurements		-----	
System errors		-----	
Calibrators	1. Signal	2. Signal	Target Value
1 :	1321	1345	0.100 ng/ml
2 :	488921	479612	57.60 ng/ml

Example: Successful L-Cal calibration data report for a quantitative assay

Calibration Data	Operator ID: 02	10/02/2002 13:35

Reagent pack calibration questionable		
Released as R. pack calib. by operator		
Test code	: TSH 0	
Unit	: uIU/l	
Lot no. reagent pack	: 160533	
Reagent pack number	: 47565	
Exp. date reagent pack	: 02/2003	
Lot Calibration		
Lot calibration date	: 09/04/2002	
Reagent pack no. for Lot Calib.	: 47565	
Lot no. of calibrator	: 160214	
Exp. date calibrator	: 02/2003	
Recommended at	: 10/04/2002	
R. Pack Calibration		
Reagent pack calibration date	: 10/07/2002	
Reagent pack no. for R. pack cal.	: 47565	
Lot no. of calibrator	: 160214	
Exp. date calibrator	: 02/2003	
Recommended at	: 10/14/2002	
Calibration Quality Criteria		
Missing values	-----	
Monotony of curve	-----	
Calibration factor	1.08	
Minimum signal	-----	
Minimum acceptable difference	-----	
Deviation of dup. measurements	1----	
System errors	-----	
Calibrators	1. Signal	2. Signal
1 :	830.9	1219
2 :	23741	23576
		Target Value
		0.000 uIU/ml
		1.44 uIU/ml

Example: Questionable R-Cal calibration data report for a quantitative assay

Calibration Data	Operator ID: 10	02/28/2002 09:07

Lot calibration was successful		
Test code	: A-HBC	
Lot no. reagent pack	: 332233	
Reagent pack number	: 2002	
Exp. date reagent pack	: 03/2002	
Lot Calibration		
Lot calibration date	: 02/28/2002	
Reagent pack no. for Lot Calib.	: 2002	
Lot no. of calibrator	: 332233	
Exp. date calibrator	: 04/2002	
Recommended at	: 05/28/2002	
R. Pack Calibration		
Reagent pack calibration date	: 02/28/2002	
Reagent pack no. for R. pack cal.	: 2002	
Lot no. of calibrator	: 332233	
Exp. date calibrator	: 04/2002	
Recommended at	: 03/05/2002	
Calibration Quality Criteria		
Missing values	----	
Slope	OK	
Min/max signal	----	
Minimum acceptable difference	OK	
Deviation of dup. measurements	--	
System errors	--	
Calibrators	1. Signal	2. Signal
1 :	49877	38862
2 :	608.8	598.4
Cut off:	35415	
Borderline area:	1.00 - 1.00	

Example: Successful L-Cal calibration data report for a qualitative assay

Explanation of the Calibration Data Report

The Operator ID is displayed in the middle of the top line. The date and time of the printout are displayed on the right side of the top line.

Test code

The test code of the assay being calibrated.

Unit

The unit of measure. A primary unit is encoded in the reagent bar code. If available, another unit can be selected in the **TEST CONDITIONS DETAILS** pop-up window on the **TEST CONDITIONS** screen (**UTILITY** folder). This field only appears on a quantitative assay report.

Lot no. reagent pack

The lot number of the reagent pack calibrated.

Reagent pack number

The unique identifier number on the reagent pack.

Exp. date reagent pack

The expiration date of the reagent pack.

Lot Calibration

Lot calibration date

The date of the last valid L-Cal for this lot of reagent.

Reagent pack no. for Lot Calib.

The identifier number of the reagent pack used to generate the L-Cal.

Lot no. of calibrator

The lot number of the assay's calibrators used in the last valid L-Cal.

Exp. date calibrator

The expiration date of the assay's calibrators used in the last valid L-Cal.

Recommended at

The date at which the next L-Cal is recommended. High volume reagent users (reagent pack used in less than 7 days) should follow the L-Cal recommendation. Lower volume users (reagent pack in use for more than 7 days) should follow the R-Cal recommendation.

R. pack Calibration

Reagent pack calibration date

The date of the last valid R-Cal for this lot of reagent.

Reagent pack no. for R. pack cal.

The identifier number of the reagent pack used to generate the R-Cal.

Lot no. of calibrator

The lot number of the assay's CalSet calibrators that were used in the last valid R-Cal.

Exp. date calibrator

The expiration date of the assay's CalSet calibrators that were used in the last valid R-Cal.

Recommended at

The date at which the next R-Cal is recommended. High volume reagent users (reagent pack used in less than 7 days) should follow the L-Cal recommendation. Lower volume users (reagent pack in use for more than 7 days) should follow the R-Cal recommendation.

Calibration Quality Criteria

Explanations for the following fields can be found in Chapter 7.4.1, CALIBRATION DATA DETAILS Pop-up Window.

Missing values

Monotony of curve (quantitative assays only)

Slope (qualitative assays only)

Calibration factor (quantitative assays only)

Minimum signal

Min/max signal (qualitative assays only)

Minimum difference (quantitative assays only)

Minimum acceptable difference (qualitative assays only)

Deviation of dupl.

System errors

Cal.(Calibrators)

1. Signal

2. Signal

Target (quantitative assays only)

Cutoff (qualitative assays only)

Borderline (qualitative assays only)

8.10 TEST CONDITIONS Report

The Test Conditions report lists the information found in the **TEST DETAILS** pop-up window (**UTILITY** folder). You can either print a report for all test buttons or a report for a single assay. The report is sorted by test number.

All displayed tests can be printed out in the **TEST CONDITIONS** screen. You can obtain a printout of a single test condition by touching the relevant test button.

Test Conditions		Operator ID: 10	02/27/2002 13:40	
Test No.	Test Code	Unit	Expected Values	
1	TSH	uIU/ml	[0.270- 4.20]
2	T4	nmol/l	[66.00- 174.0]
3	FT4	pmol/l	[13.00- 23.00]
4	T-UP	TBI	[0.800- 1.30]
5	T3	nmol/l	[1.30- 3.10]
6	FT3	pmol/l	[4.00- 7.80]
17	HCGSTAT	mIU/ml	[0.500- 5.00]
20	TNTSTAT	ng/ml	[0.000- 0.100]
21	CKMBSTAT	ng/ml	[0.000- 5.00]

A Test Conditions report printed from the **TEST CONDITIONS** screen

Test Conditions		Operator ID: 10	02/27/2002 13:40	
Test No.	Test Code	Unit	Expected Values	
1	TSH	uIU/ml	[0.270- 4.20]

A Test Conditions report printed from the **TEST CONDITIONS DETAILS** pop-up window

Explanation of the Test Conditions Report

Test No.

The test number, encoded in the reagent bar code, assigned to the assay; however, you can change the number in the **TEST CONDITIONS DETAILS** pop-up window (**UTILITY** folder).

Test Code

The test abbreviation assigned to the assay.

Unit

The unit of measure. A primary unit is encoded in the reagent bar code. If available, another unit can be selected in the **TEST CONDITIONS DETAILS** pop-up window (**UTILITY** folder).

Expected Values

The expected values for the assay. These values are encoded in the reagent bar code; however, they can be changed in the **TEST CONDITIONS DETAILS** pop-up window (**UTILITY** folder).

8.11 MESSAGE HISTORY Report

The Message History report is a printout of alarm messages currently stored in the system. Once the upper limit of 200 messages stored is exceeded, the oldest messages are overwritten on a first in, first out basis.

To print out the required alarm messages: Enter the lines to be printed out in the **Up to line** field in the **PRINT MESSAGE HISTORY** pop-up window on the **MESSAGE HISTORY** screen (**UTILITY** folder) and touch **Print**.

Message History		Operator ID: 01	02/27/2002 09:18	
Message	Alarm no	Pos/no	Date	Time
Main power on			02/27/2001	09:16
Main power off			02/27/2001	09:11
LFC is recommended	60-01-01		02/26/2001	12:09
LFC is recommended	60-01-01		02/27/2002	08:26
A tray was missing on A-Line	61-02-02		02/27/2002	08:23
A tray was missing on A-Line	61-02-02		02/27/2002	08:22
All racks on A-Line were loaded	61-02-01		02/27/2002	08:05
LFC is recommended	60-01-01		02/26/2002	17:15
All racks on A-Line were loaded	61-02-01		02/26/2002	16:25
Premature LLD hovering on assay rackpack	37-01-05	100	02/26/2002	16:23
Premature LLD hovering on assay rackpack	37-01-05	100	02/26/2002	16:20
Premature LLD hovering on assay rackpack	37-01-05	100	02/26/2002	16:18
Premature LLD hovering on assay rackpack	37-01-05	100	02/26/2002	16:18
All racks on A-Line were loaded	61-02-01		02/26/2002	15:53
All racks on A-Line were loaded	61-02-01		02/26/2002	15:03
LFC is recommended	60-01-01		02/26/2002	14:47
All racks on A-Line were loaded	61-02-01		02/26/2002	14:11
Main power on			02/26/2002	13:51
Main power off			02/26/2002	04:07
All racks on A-Line were loaded	61-02-01		02/25/2002	11:01
All racks on A-Line were loaded	61-02-01		02/25/2002	10:52
All racks on A-Line were loaded	61-02-01		02/25/2002	10:46
All racks on A-Line were loaded	61-02-01		02/25/2002	10:41
All racks on A-Line were loaded	61-02-01		02/25/2002	09:26
All racks on A-Line were loaded	61-02-01		02/25/2002	09:00
All racks on A-Line were loaded	61-02-01		02/25/2002	08:56
A tray was missing on C-Line	63-02-01		02/25/2002	08:28
All racks on A-Line were loaded	61-02-01		02/25/2002	08:05
All racks on A-Line were loaded	61-02-01		02/25/2002	07:56
All racks on A-Line were loaded	61-02-01		02/25/2002	07:30

Explanation of the Message History Report

Message

The alarm message is listed here. Please refer to Chapter 3, Instrument Alarms, in the User's Guide for more detailed information.



Certain alarms differ according to the system used (Rack or Disk).

Date

The date the alarm occurred. The most recent alarm is listed first. The remaining alarms are listed in reverse chronological order.

Time

The time the alarm occurred. The most recent alarm is listed first. The remaining alarms are listed in reverse chronological order.

Alarm no

The alarm number is listed here, according to the alarm message in the first column. The exact meaning of which depends upon the type of alarm is described in chapter 3, Instrument Alarms, in the User's Guide.

Pos/no

Depending on the type of alarm and the affected component, the alarm report indicates the position number of the reagent pack on the reagent disk, the position of the rack (if a rack system is used), the sequence number or the number of the test. For more information about the alarms refer to the chapter 2.7, ALARM Pop-up Window, here in the Software Guide and the chapter with the instrument alarms in the User's Guide.

**Elecsys 2010
User's Guide**

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1. General Troubleshooting

1.1 Introduction

To identify and isolate problems effectively, you must understand the theory of operation, operating procedures, emergency procedures and chemistry reaction descriptions covered in this manual. Follow a logical and sequential series of steps to isolate a problem into one or more of the following areas:

Chemistry problems:

- reagent
- instrument
- sample
- operator error.

Instrument problems:

- electrical/electronic
- mechanical
- operator error.

Software problems:

- faulty system parameter on disk or disk load error
- operator error.

Facility problems:

- heat
- humidity
- power
- water.

Your primary troubleshooting responsibility lies in the following areas:

- reagent preparation and storage
- sample considerations
- general software operations
- basic component replacement
- operator technique in overall operation of the instrument
- maintenance.



The basic operator is not responsible for troubleshooting electrical problems, except as covered in the operator's manual. Do not attempt removal of electronic components.

When troubleshooting, review the alarms and isolate the problem to the area denoted by the alarms. In many cases, you may be able to find the problem, correct it and resume test processing.

The remainder of this section provides you with instructions and guidelines to aid in isolating problems.

1.2 Immunoassay Troubleshooting

Mechanical problems are evident when the analyzer displays an alarm message. A chemistry problem may display a data flag, or may only become evident with an unexpected result.

Deciding that a problem exists is the first step in the process. The following situations may require troubleshooting:

- error codes on calibration documentation
- data flags on control or patient samples
- quality control sample results outside established range
- patient tests with unexpected results.

When troubleshooting a problem, first access the **MESSAGES** screen (**UTILITY** folder) and print a message history. Print the last 10-20 messages and use this report to assist you.

To troubleshoot effectively, eliminate extraneous information and pinpoint the problem. Use the calibration documentation, quality control results or patient results to decide which of the following conditions apply, and perform the associated checks outlined in the following sections:

- single sample affected
- single assay affected.

Reagents, Calibrators and Controls

Sometimes conditions arise that cannot be detected by the analyzer. These conditions do not generate alarms and therefore must be detected by the operator. When one or more of these conditions are present, test results can be extremely high, low or erratic.

To identify the cause of high, low or erratic test results, first verify the handling of reagents, calibrators and controls by answering the following questions.

When preparing or handling reagents, calibrators and controls, always read the package insert.

When handling reagents:

Has the catalog number changed?

Has the lot number changed? Does it match the lot number in the 'Reagent Details' pop-up window?

Was the reagent stored appropriately?

When reconstituting/handling calibrators:

Has the lot number changed?

What is the correct reconstitution volume?

Was the correct amount of time allowed for reconstitution?

Was the CalSet at room temperature prior to operation?

What is the recommended storage?

What is the expiration date of the calibrator lot?

What is the expiration date of the reconstituted material?

Was fresh, bacteria-free, deionized water used in reconstitution?

Were volumetric pipettes used (where appropriate)?

When reconstituting controls:

What is the correct reconstitution volume?

Was the correct amount of time allowed for reconstitution?

What is the recommended storage?

What is the expiration date of the control lot?

What is the expiration date of the reconstituted material?

Was fresh, bacteria-free, deionized water used in reconstitution?

Were volumetric pipettes used (where appropriate)?

Single Sample

Check for:

- sufficient sample volume, including adequate sample container dead volume
- sample integrity (fibrin, hemolysis, icterus, lipemia)
- appropriate type of sample (serum, plasma)
- bubbles in the sample cup or tube
- sample reproducibility
- proper tube placement in the sample carrier.

Single Assay

Check for:

- calibrators not at room temperature prior to operation
- improperly prepared calibrators
- expired reagent(s)
- expired calibrators
- calibrators used more than five times
- correct lot number in the **REAGENT DETAILS** pop-up window.

1.3 General Instrument Troubleshooting

When troubleshooting a problem, first access the **MESSAGES** screen (**UTILITY** folder) and print a message history. Print the last 10-20 messages and use this report to assist you.

Electric power is not available

If you are having problems turning the analyzer on, follow the steps below:

1. Are the operation ON/OFF switch and circuit breaker turned OFF?
If yes, go to step 2.
If no, go to step 3.
2. Turn on both power switches.
3. Is the power cable plug disconnected at either the instrument or the outlet?
If yes, go to step 4.
If no, go to step 5.
4. Firmly connect the power cable.
5. Is the outlet working?
If yes, go to step 9.
If no, go to step 6.
6. Check the circuit breaker in the laboratory distribution box.
7. Is the line voltage adequate?
If yes, go to step 9.
If no, go to step 8.
8. Use line power of the proper line voltage.
9. Call Technical Support.

If for any other reason you have problems with the power to your analyzer, call Technical Support.

Cannot access another software screen

If you are unable to access another software screen, follow the steps below:

1. Power OFF the analyzer at the circuit breaker.
2. Check the cabling between the touchscreen and the analyzer.
3. Power ON the analyzer at the circuit breaker. If you are still unable to access another screen, then call Technical Support.

The touchscreen does not come on

If you are having problems with the touchscreen, follow the steps below:

1. Is the operation ON/OFF switch on the front of the analyzer turned off?
If yes, go to step 2.
If no, go to step 3.
2. Turn the operation switch ON. Does the touchscreen come on?
If no, go to step 3.
3. Is the cable between the touchscreen and the instrument disconnected?
If yes, go to step 4.
If no, go to step 5.
4. Firmly connect the cable.
5. Call Technical Support.

The touchscreen is hard to see

If the touchscreen is difficult to see, follow the steps below:

1. Is the touchscreen dirty?
If yes, go to step 2.
If no, go to step 3.
2. Gently wipe the surface with a dry cloth.
3. Is the ambient lighting too bright?
If yes, go to step 4.
If no, go to step 5.
4. Either reduce the brightness of the ambient lighting or change the direction of the adjustable monitor face.
5. Call Technical Support.

The solid waste tray does not come out or produces irregular sounds

If you are having problems removing the solid waste tray or unusual sounds are coming from the solid waste tray area, follow the steps below:

1. Are tray and liner properly seated?
If yes, go to step 3.
If no, go to step 2.
2. Reseat the tray and liner.
3. Are there stray cups or tips behind the tray?
If yes, go to step 4.
If no, go to step 5.
4. Remove the stray cups and tips and replace the tray and liner.
5. Call Technical Support.

The reagent disk cover does not open/close

If you are having problems opening or closing the reagent disk cover, follow the steps below:

1. The reagent disk cover is keyed. Is the reagent disk cover properly oriented for placement?
If yes, go to step 3.
If no, go to step 2.
2. Make sure that the reagent disk cover fits into the key before locking.
3. Is there an obstacle around the cover?
If yes, go to step 4.
If no, go to step 5.
4. Remove the obstacle.
5. Call Technical Support.

The sample disk does not move

If the sample disk does not move properly, follow the steps below:

1. Is the sample disk seated properly?
If yes, go to step 3.
If no, go to step 2.
2. Remove and reseal the sample disk.
3. Is there an obstacle around the sample disk?
If yes, go to step 4.
If no, go to step 5.
4. Remove the obstacle.
5. Call Technical Support.

Trouble placing a reagent pack on the reagent disk

If you are having problems placing a reagent pack on the reagent disk, follow the steps below:

1. Reagent packs are keyed for proper placement. Is the reagent pack properly oriented?
If yes, go to step 3.
If no, go to step 2.
2. Reorient the reagent pack (i.e., the white cap and the bar code facing toward the outside of the reagent disk).
3. Is there an obstacle beneath the reagent disk?
If yes, go to step 4.
If no, go to step 5.
4. Remove the obstacle.
5. Is the reagent pack damaged?
If yes, go to step 6.
If no, go to step 7.
6. Replace the reagent pack.
7. Call Technical Support.

Trouble replacing a tip/cup tray

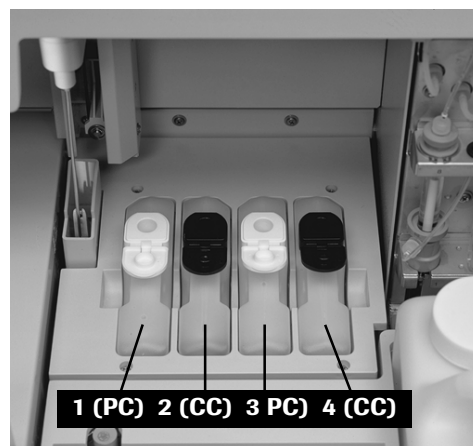
If you are having problems replacing a tip or cup tray, follow the steps below:

1. Tip and cup trays are keyed for proper placement. Is the tip or cup tray properly oriented?
If yes, go to step 3.
If no, go to step 2.
2. Remove and reseal the tip or cup tray.
3. Is there an obstacle around the tray?
If yes, go to step 4.
If no, go to step 5.
4. Remove the obstacle.
5. Is the tray damaged or deformed?
If yes, go to step 6.
If no, go to step 7.
6. Replace the tray.
7. Call Technical Support.

Trouble replacing a system reagent (ProCell or CleanCell)

If you are having problems replacing a ProCell or CleanCell reagent bottle, follow the steps below:

1. The system reagent bottles are keyed for proper placement. Are you placing the bottle in its appropriate position?
If yes, go to step 3.
If no, go to step 2.
2. Remove the bottle and check the position before placing the reagent into its proper place (i.e., ProCell (PC) in positions 1, 3 and CleanCell (CC) in positions 2, 4).
3. Is there an obstacle beneath the system reagent bottle?
If yes, go to step 4.
If no, go to step 5.
4. Remove the obstacle.
5. Is the system reagent bottle damaged or deformed?



Sometimes the system reagent bottle appears to bulge until the cap is opened. You may also be able to fit the bottle in the compartment after opening the cap.

- If yes, go to step 6.
If no, go to step 7.
6. Replace the system reagent bottle.
 7. Call Technical Support.

Trouble replacing the distilled water container

If you are having problems replacing the distilled water container, follow the steps below:

1. The distilled water container must be properly oriented for placement (i.e., verify that the cap is closest to the rear of the analyzer. Is the container facing the right way?
If yes, go to step 3.
If no, go to step 2.
2. Reseat the container and gently push down until you feel a snap indicating that the bottle is connected.
3. Is there an obstacle around the distilled water container?
If yes, go to step 4.
If no, go to step 5.
4. Remove the obstacle.
5. Is the distilled water container damaged or deformed?
If yes, go to step 6.
If no, go to step 7.
6. Replace the distilled water container.
7. Call Technical Support.

Trouble replacing the solid waste tray

If you are having problems replacing the solid waste tray, follow the steps below:

1. Does the Clean-Liner fit properly (i.e., the opening in the sliding door must point to the rear of the analyzer) and is not damaged or bent?
If yes, go to step 3.
If no, go to step 2.
2. Try a different Clean-Liner.
3. Is there an obstacle around the solid waste tray?
If yes, go to step 4.
If no, go to step 5.
4. Remove the obstacle.
5. Is the solid waste tray damaged or deformed?
If yes, go to step 6.
If no, go to step 7.
6. Replace the solid waste tray.
7. Call Technical Support.

Empty liquid waste container causes an alarm

If your empty liquid waste container gives an alarm stating that the container is full, follow the steps below:

1. Is there an obstacle causing the tray on which the container rests, to remain in the down position (i.e., is it still activating the sensor)?
If yes, go to step 2.
If no, go to step 3.
2. Remove the obstacle.
3. Call Technical Support.

S/R probe or sipper probe tip does not descend to the liquid surface

If the S/R probe or sipper probe tip does not descend to the liquid surface, follow the steps below:

1. Are there bubbles on the liquid surface?
If yes, go to step 2.
If no, go to step 3.
2. Eliminate the bubbles in the sample container with an applicator stick.
3. Did the probe tip touch something during descent?
If yes, go to step 4.
If no, go to step 5.
4. Remove the obstacle.
5. There could be a problem with water quality. Access the **VOLTAGE MONITOR** screen (**UTILITY** folder).
If the S/R probe LLD voltage is > 2.00 V, then clean the S/R probe.
7. If the voltage is > 2.00 V, call Technical Support.

Results do not print automatically

If results do not print automatically, follow the steps below:

1. Is the printer powered ON and on line (i.e., the green light above "Ready" is illuminated)?
If yes, go to step 3.
If no, go to step 2.
2. Turn the printer ON. Verify the green "Ready" light is on.
3. Is automatic printing selected (button is light blue) on the **DOCUMENTATION SETUP** screen (**UTILITY** folder)?
If yes, go to step 5.
If no, go to step 4.
4. Specify a proper printing mode by referring to the description in Chapter 7, UTILITY – Software Guide.
5. Call Technical Support.

Bubbles in the pipettors

If you see bubbles in either the S/R pipettor or the sipper pipettor, follow the steps below:

1. Are there bubbles in the S/R pipettor?
If yes, go to step 3.
If no, go to step 2.
2. Are there bubbles in the sipper pipettor?
If yes, go to step 4.
3. Perform an S/R pipettor prime from the **MAINTENANCE** screen (**UTILITY** folder). Enter 10 cycles. Go to step 5.
4. Perform a sipper pipettor prime from the **MAINTENANCE** screen (**UTILITY** folder). Enter 10 cycles. Follow this by a Measuring Cell preparation. Enter 5 cycles.
5. Are there still bubbles in the pipettor?
If yes, repeat step 3 or 4 for the appropriate pipettor.
6. After the second pipettor prime, do bubbles remain in the pipettor?
If yes, go to step 7.
7. Call Technical Support.

2. Data Alarms

2.1 Data Alarms Table

The data alarms table on the following pages lists several pieces of information. Included in the table is an alarm level. This number indicates the priority of the alarm. The priority is from 1 to 8, with 1 being the highest priority and 8 being the lowest priority. Several data alarms may occur for a sample; however, only the alarm with the highest priority is displayed on the screen or printed next to the result. If two or more data alarms for a result occur with the same priority, the one that occurred first goes with the result. Any other data alarms with lower priorities that may have been generated cannot be printed or viewed.

The Message column shows the data alarm message displayed on the on-line result printout. The Cause or Description column tells you what the alarm means, or what caused the alarm condition. The Remedy column lists suggestions to correct the problem.

Three additional columns provide information as to whether you can expect to obtain a result for the sample. The No Result column shows a check mark if the alarm causes the system to give no result for the sample. The System Block column shows a check mark if the alarm causes the system to block the result. The Data Alarm column shows the data alarm that accompanies the result.

Alarm Abbreviations

The following table is a brief listing of the alarm levels and their abbreviations. For detailed information on the alarm levels, refer to Chapter 3, Instrument Alarms.

Alarm Level	Abbreviation
Emergency Stop	E. Stop
Stop	Stop
Partial Stop	P. Stop
Analyzer Stop	A. Stop
Line Stop	L. Stop
Sampling Stop	S. Stop
Rack Stop	R. Stop

Classification of Results

Results can be classified in three ways:

Not Flagged and Not Blocked

These results are automatically released by the system; a valid result within the expected values range.

Flagged and Not Blocked

These results are automatically released by the system; a valid result, but it is either outside the expected values range or outside the measuring range.

Flagged and Blocked

These results are system blocked and cannot be released by the operator. All system blocked samples have a result of "No value".

2.2 Data Flags

Alarm No.	Alarm Message		Cause or Description	Remedy	No Result?	System Block?	Data Alarm
	No.	Level					
1	1	Power failure - operation stopped	Test cancelled due to power failure or power off. Sample(s) may be excluded; refer to printout.	Correct condition and rerun any excluded samples.	✓	✓	1S
2	2	E. Stop - operation stopped	Test cancelled due to E. Stop. Sample(s) may be excluded; refer to printout.	Correct alarm condition and rerun any excluded samples.	✓	✓	1S
3	3	Stop - operation stopped by operator	Operation stopped by operator. Sample(s) may be excluded; refer to printout.	Correct alarm condition and rerun any excluded samples.	✓	✓	3S
4	4	P. Stop/A. Stop - operation stopped	Test cancelled due to P. Stop, A. Stop or L. Stop. Sample(s) may be excluded; refer to printout.	Correct alarm condition and rerun any excluded samples.	✓	✓	4S
5	4	S. Stop - operation stopped	Sampling is stopped due to S. Stop. Sample(s) in process will be completed.	Correct alarm condition and continue with sample(s) to be processed.	✓	✓	5S
6	5	Instrument handling error - determination not performed	Test cancelled due to instrument handling error. Sample(s) may be excluded; refer to printout.	Rerun any excluded samples.	✓	✓	6S

Alarm No.	Alarm Level	Message	Cause or Description	Remedy	No Result?	System Block?	Data Alarm
7	6	Sample short	The sample volume is insufficient.	a. Fill the sample container with the sample, then rerun. Refer to Section Technical Data - Reference Guide, for sample container dead volumes. b. If the sample visually appears sufficient, call Technical Support.	✓	✓	7S
8	6	Assay reagent short	The assay reagent volume is insufficient or calibration data are not available for this reagent.	a. Check the number of tests remaining on the INVENTORY screen. Replace the reagent pack, if necessary. b. Perform a Reagent Scan after reagent replacement; if the alarm recurs, call Technical Support.	✓	✓	8S
9	6	Diluent short	The diluent volume is insufficient.	a. Check the number of mls remaining on INVENTORY screen. Replace the diluent, if necessary. b. Perform a Reagent Scan after diluent replacement; if the alarm recurs, call Technical Support.	✓	✓	9S
10	6	Pretreatment reagent short	The pretreatment reagent volume is insufficient.	a. Check the number of tests remaining on INVENTORY screen. Replace the pretreatment reagent, if necessary. b. Perform a Reagent Scan after reagent replacement; if the alarm recurs, call Technical Support.	✓	✓	10S

Alarm No.	Alarm Level	Message	Cause or Description	Remedy	No Result?	System Block?	Data Alarm
12	7	Reagent disk temperature out of range	Reagent disk temperature is out of range. An initial check occurs at 30 minutes after power ON at the circuit breaker. The temperature is checked continuously thereafter.	a. Verify that the reagent disk cover is securely in place. b. Check that the fans at the back of the analyzer are operating normally and are free of obstructions. c. Check that the room temperature is between 18 °C and 32 °C. d. If the alarm recurs, call Technical Support.			12
13	7	Incubator temperature out of range	Incubator temperature is out of range. An initial check occurs at 30 minutes after power ON at the circuit breaker. The temperature is checked continuously thereafter.	a. Check that the fans at the back of the analyzer are operating normally and are free of obstructions. b. Check that the room temperature is between 18 °C and 32 °C. c. If the alarm recurs, call Technical Support.			13
14	7	Measuring cell temperature out of range	Measuring cell temperature is out of range. An initial check occurs at 30 minutes after power ON at the circuit breaker. The temperature is checked continuously thereafter.	a. Verify the temperature of ProCell/CleanCell. b. Check that the fans at the back of the analyzer are operating normally and are free of obstructions. c. Check that the room temperature is between 18 °C and 32 °C. d. If the alarm recurs, call Technical Support.			14

Alarm No.	Alarm Level	Message	Cause or Description	Remedy	No Result?	System Block?	Data Alarm
15	7	PC/CC temperature out of range	ProCell/CleanCell temperature is out of range. An initial check occurs at 30 minutes after power ON at the circuit breaker. The temperature is checked continuously thereafter.	a. Check that the fans at the back of the analyzer are operating normally and are free of obstructions. b. Check that the room temperature is between 18 °C and 32 °C. c. If the alarm recurs, call Technical Support.			15
16	7	PC/CC short	ProCell/CleanCell volume is insufficient.	a. Check the remaining volume on the INVENTORY screen. Replace the system reagent, if necessary. b. If the alarm recurs after replacement, call Technical Support.	✓	✓	16S
17	7	ADC data abnormal	Analog to digital converter (ADC) data is abnormal.	Call Technical Support.	✓	✓	17S
18	-	Not active in this version.					
19	-	Not active in this version.					
20	-	Not active in this version.					
21	-	Not active in this version.					
23	-	Not active in this version.					

Alarm No.	Level	Message	Cause or Description	Remedy	No Result?	System Block?	Data Alarm
24	6	Calculation error	Internal calculation error occurred.	Rerun the sample	✓	✓	24S
25	6	No calibration data, result calculation not possible	There is no valid calibration data in the system for this reagent pack (i.e., a new assay on the analyzer).	Rerun the samples after there is a valid L-Cal or R-Cal stored in the system.	✓	✓	25S
26	8	Previous calibration data used	Previous calibration data was used for result calculation. The attempted calibration was questionable or failed.	a. Check the calibrators and reagents. Repeat the calibration. b. Rerun the samples after a successful calibration is obtained.			26
27	S	Result blocked by system					S
28	B	Result blocked by user					B
29	R	Result released by user					R
31	6	Premature LLD R. Disk: assay reagent	A premature LLD signal was detected during reagent pipetting, causing the S/R probe to hover over the reagent pack.	a. Wipe dry the lids on the affected reagent pack. b. Check for bubbles in the affected reagent pack. c. Rerun the affected sample(s). d. If the error recurs, call Technical Support.	✓	✓	31S

Alarm No.	Alarm Level	Message	Cause or Description	Remedy	No Result?	System Block?	Data Alarm
32	6	Premature LLD R. Disk: diluent	A premature LLD signal was detected during reagent pipetting, causing the S/R probe to hover over the diluent reagent pack.	a. Wipe dry the lids on the affected reagent pack. b. Check for bubbles in the affected reagent pack. c. Rerun the affected sample(s). d. If the error recurs, call Technical Support.	✓	✓	32S
33	6	Premature LLD R. Disk: pretreatment	A premature LLD signal was detected during reagent pipetting, causing the S/R probe to hover over the pretreatment reagent pack.	a. Wipe dry the lids on the affected reagent pack. b. Check for bubbles in the affected reagent pack. c. Rerun the affected sample(s). d. If the error recurs, call Technical Support.	✓	✓	33S
34	-	Not active in this version					
35	6	Film detected on assay reagent	Foam or film was detected above reagent.	Remove foam/film with an applicator stick and rerun the affected sample.	✓	✓	35S
36	6	Film detected on diluent	Foam or film was detected above diluent.	Remove foam/film with an applicator stick and rerun the affected sample.	✓	✓	36S
37	6	Film detected on pretreatment	Foam or film was detected above pretreatment reagent.	Remove foam/film with an applicator stick and rerun the affected sample.	✓	✓	37S
38	6	Film detected on PC/CC	Foam or film was detected above PC/CC.	Remove foam/film with an applicator stick and rerun the affected sample.	✓	✓	38S
39	-	Not active in this version					

Alarm No.	Alarm Level	Message	Cause or Description	Remedy	No Result?	System Block?	Data Alarm
40	6	PC signal level out of range	During run preparation, the ProCell count level was out of range. The ProCell signal was < 200 or > 400 counts. The ProCell has evaporated or may be contaminated.	a. Check for bubbles in the ProCell bottle. b. Try a new bottle of ProCell. c. Rerun all flagged samples. d. If the error recurs, call Technical Support.			40
41	6	PC liquid level check failed	ProCell liquid level check failed. The ProCell volume was inadequate for run preparation.	a. Replace the low volume bottle with a new bottle. b. Rerun all flagged samples. c. If the error recurs, call Technical Support.			41
42	6	Measuring cell current out of range	The measuring cell current was out of range when checked during run preparation.	a. Perform a Liquid Flow Cleaning from the MAINTENANCE screen (UTILITY folder). Refer to Section 4.7, Perform Liquid Flow Cleaning for details. b. Rerun all flagged samples. c. If the error recurs, call Technical Support.	✓	✓	42S
43	6	Measuring cell current check failed	Measuring cell current check failed. The ProCell volume was inadequate for run preparation.	a. Replace the low volume bottle with a new bottle. b. Rerun all flagged samples. c. If the error recurs, call Technical Support.			43

Alarm No.	Alarm Level	Message	Cause or Description	Remedy	No Result?	System Block?	Data Alarm
44	6	PC/CC temperature unstable	ProCell/CleanCell temperature was unstable.	ProCell and CleanCell must be at 28 °C before operation. Either bring the reagent to temperature or place on the analyzer approximately 15 minutes prior to operation.			44
45	6	Abnormal aspiration	Either the sample volume was insufficient or a clot was detected during sample pipetting.	a. Check sample volume. b. Check sample for fibrin, remove any clots and rerun.	✓	✓	45S
46	6	Potential carryover	Carryover from the previous sample may have occurred.	Rerun the sample.			46
47	6	Sample Bar code ID error	The sample ID that was scanned just prior to pipetting is different from the ID scanned during the sample scan. All tests for the sample were cancelled.	Verify that sample tubes are not removed until the STATUS screen reads "Proc" or "Compl."	✓	✓	47S
48	6	Result below expected value range	The sample concentration was below the lower limit of the expected values.	For information only.			48
49	6	Result above expected value range	The sample concentration was above the upper limit of the expected values.	For information only.			49

Alarm No.	Alarm Level	Message	Cause or Description	Remedy	No Result?	System Block?	Data Alarm
50	6	Result below measuring range	The sample concentration was below the lower limit of the measuring (reportable) range.	Report the result as less than the LDL of the assay			50
51	6	Result above measuring range	The sample concentration was above the upper limit of the measuring (reportable) range.	Dilute the sample and reassay the diluted sample.			51
52	8	Result generated with expired reagent pack	An expired reagent pack was used for the determination.	For information only			52
53	6	No sample	No sample was set on the sample disk.	Set the sample on instrument.	✓	✓	53S
54	6	Sample LLD malfunction	LLD does not function, e.g. due to a dirty probe.	a. Clean the S/R probe. b. Access the MAINTENANCE screen and perform S/R pipettor prime 20 times. c. Rerun the affected sample.d. If the alarm recurs, call Technical Support.	✓	✓	54S
55	6	Sample LLD noise	An LLD error occurred due to noise.	a. Check for bubbles in the sample. b. Rerun the affected sample. c. If the alarm recurs, call Technical Support.	✓	✓	55S

Alarm No.	Alarm Level	Message	Cause or Description	Remedy	No Result?	System Block?	Data Alarm
56	6	Measuring cell current range over during operation	The measuring cell current range was exceeded during operation.	a. Rerun the sample. b. If the alarm recurs, call Technical Support.			56
57	6	Instrument factor A was set to 1.0	The instrument factor A was set to 1.0 by the system.	For information only.			57
58	6	Signal level below limit	The signal level was below the defined limit.	a. Rerun the sample. b. If the alarm recurs, call Technical Support.	✓	✓	58S

2.3 Special Data Flags

There are three data flags that appear in conjunction with the previous data alarms. These flags denote that the data is blocked or released. They are suffixed to the numeric alarms and are displayed on the RESULTS screen and printed on the patient reports. The flags are as follows:

- S blocked by the system
- B blocked by the operator
- R released by the operator.

Refer to the example of the Results report shown below.

Test Results		Operator-Id: 01		23.02.2000 17:05	

Control-Id	: PC U1	Seq-No.	: 213	Documented	
Rotor - Pos.	: 4-10	Sampling Date	: 23.02.2000 12:27		
Test Code	Result	Unit	Dil.	Normal Range	Note Ready Flag

TSH 0	1.58	uIU/ml	[1.36- 1.96]	12:45 45s
T4 1	97.17	nmol/l	[77.97- 119.4]	12:46
PROG 1	6.83	ng/ml	[0.000- 0.000]	12:47 49
AFP 1	10.23	IU/ml	[6.92- 12.84]	12:47
Flags : 45 = Abnormal aspiration					
49 = Above normal (expected) range					
S = System Block					

3. Instrument Alarms

3.1 General Description


When an instrument alarm occurs while instrument power is ON, the color of the status line changes on the screen. The alarm code is displayed along with a brief message. Warning, S. Stop and R. Stop messages appear as red text on a yellow status line. L. Stop, A. Stop, P. Stop and Stop alarms appear as yellow text on a red status line. E. Stop alarms appear as yellow text on a flashing red status line. Refer to the examples below.

Operation	Sample bar code not read: 38-01-02 25 Warning				
Inventory	Orders	Results	QC	Status	Utility

Status line with a warning, S. Stop or R. Stop alarm

P. Stop	Gripper Z-movement : 18-03-04 P.Stop				
Inventory	Orders	Results	QC	Status	Utility

Status line with an L. Stop, A. Stop, P. Stop or Stop alarm



P. Stop	GP controller : 29-01-01 E.Stop				
Inventory	Orders	Results	QC	Status	Utility

Status line with an E. Stop alarm

When the alarm text appears it overwrites the usual status line text, but leaves the analyzer status visible. In the first example, a sample bar code alarm occurred at position 25 on the sample disk. The alarm status line remains on the screen until the **ALARM** key is pressed. Pressing **ALARM** clears the alarm, returns the status line to normal and accesses the **ALARM** pop-up window.

If the green light next to the **ALARM** key is on, the audible alarm is OFF. If an alarm occurs, the status line changes, but you will not hear the alarm. If the green light next to the **ALARM** key is off, the audible alarm is ON. If an alarm occurs, you will see a change on the status line, as well as hear the alarm. Use the **Buzzer Off** button in the **ALARM** pop-up window to activate or deactivate the audible alarm.

ALARM Pop-up Window

The first alarm that occurs appears on the status line. Additional alarms must be viewed in the **ALARM** pop-up window. When you press **ALARM**, a pop-up window appears displaying the last 10 alarm messages. You can delete these messages from the window, but they are still available in Message History. The alarms appear in chronological order on the window. You can print a history of alarm message from the **PRINT MESSAGE HISTORY** pop-up window in the **MESSAGE HISTORY** screen (**UTILITY** folder).

Multiple occurrences of the same alarm are NOT listed in this window. Therefore, you may wish to clear the alarms each time you access this window. All occurrences of alarms can be found in Message History.

Stand-by
Operator ID: 47
14:30

Inventory
Orders
Results
QC
Status
Utility

Alarms

Message	Alarm no.	Pos./no	Level	Time
All Racks on A-Line were loaded	61-02-01		R. Stop	19:02
System reagent bottle change over	37-07-01	26	Warning	15:15
Sample short (no LLD before z-max)	35-03-01	027-3	Warning	17:29
Improper reagent pack for analyzer	58-01-01	6	Warning	10:58
Sample volume insufficient or clot pip.	49-01-01	213-1	Warning	10:37
B-Line transfer	71-01-03		L. Stop	10:41
Liquid waste container is full	24-01-01		P. Stop	13:14
No LLD of assay reagent for test no. x	37-01-01	60	Warning	12:53

Buzzer
Off

Message
Clear

Close

Example of ALARM pop-up window

Alarm Codes

Check the alarms in the tables contained in this section. Take appropriate troubleshooting measures, as noted for each alarm. Instrument alarms are divided into the following groups listed in order of priority:

- E. Stop: Emergency Stop. The instrument immediately stops operation. As soon as the instrument is in Stand-by, take appropriate measures to eliminate the error. If an alarm at another level occurs at the same time as the E. Stop alarm, the E. Stop alarm takes priority and appears on the status line. Perform a system reset in the **MAINTENANCE** screen. This alarm applies to the disk and rack systems.
- Stop: The instrument stops operation within 20 seconds. As soon as the instrument is in Stand-by, take appropriate measures to eliminate the error. Perform a system reset in the **MAINTENANCE** screen. This alarm applies to the disk and rack systems.
- P. Stop: Partial Stop. Part of the instrument is no longer able to continue operation. Additional test items are inhibited, but current operation continues until it is complete. Allow the analyzer to return to Stand-by on its own, or once current operations are complete (e.g., your last sample prints), press **STOP** to return the analyzer to Stand-by. Take appropriate measures to eliminate the error and perform a system reset in the **MAINTENANCE** screen. This alarm applies to the disk and rack systems.
- A. Stop: Analyzer Stop. The analyzer is no longer able to continue operation. As soon as the entire system is in Stand-by, take appropriate measures to eliminate the error. Perform an L. and A. Reset All in the **MAINTENANCE** screen. This alarm is equivalent to P. Stop on the disk system.
- L. Stop: Line Stop. All lines stop operation. Additional tests are inhibited, but the analyzer continues operation until samples in process are completed. As soon as the entire system is in Stand-by, take appropriate measures to eliminate the error. Perform an L. and A. Reset All in the **MAINTENANCE** screen. This alarm is only applicable to the rack system.
- S. Stop: Sampling Stop. The sampling operation is forced to stop. Any samples in process are completed before the analyzer goes into Stand-by. If an error caused the analyzer to enter S. Stop, take appropriate measures to eliminate the error when the analyzer returns to Stand-by. This alarm is equivalent to R. Stop on the rack system.
- R. Stop: Rack Stop. The rack loader stops supplying racks to the line. The analyzer continues to operate. If an error caused the analyzer to enter R. Stop, take appropriate measures to eliminate the error when the analyzer returns to Stand-by. This alarm is equivalent to S. Stop on a disk system.
- Warning: The instrument continues to operate. A warning alerts you to a situation of which you should be aware. However, the analyzer continues to process samples. Take the appropriate measures to eliminate the warning condition when the analyzer returns to Stand-by, if necessary.

Description of Instrument Alarms Table

The instrument alarms table is arranged in order of alarm number. The table also includes the alarm code, a description and remedy. Shown below is an example of the instrument alarms table and brief explanation of its contents:

Alarm No.: The alarms are listed in numerical order. When an alarm occurs, look for the alarm number first, then proceed to the Alarm Message.

Alarm Message: This column indicates the descriptive name of the alarm condition. It is also the text that appears on the status line.

Alarm No.	Level	Alarm message	Alarm Description	Remedy
11_01_01	Stop	R.Disk didn't leave home pos.at reset 11-01-01	The reagent disk did not move out of the home position while the instrument was resetting itself. : Home Position detection, (mode 3-1)	a. Check for proper placement of the reagent cover. b. Perform a system reset from the MAINTENANCE screen. c. If the error recurs, call Technical Support.
11_01_02	Stop	R.Disk didn't reach home pos.at reset 11-01-02	The reagent disk did not reach or stop at the home position while the instrument was resetting itself. : Home Position detection, (mode 3-2)	
11_01_03	Stop	R.Disk didn't reach pos. 1 at reset 11-01-03	The reagent disk did not reach or stop at Position 1 while the instrument was resetting itself. : Count detection, (mode 5-1,5-2)	
11_01_05	P.Stop/ Stop	R.Disk didn't reach home pos.at reset 11-01-05	The reagent disk did not reach or stop at the R2 (Cap/Open position) position correctly. However, this does not apply when the reagent disk rotates from R1 position to R2 position in CCW rotation. : Count detection, (mode 2-1)	a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
11_01_07	P.Stop/ Stop	R. Disk didn't reach mixing pos. properly 11-01-07	The reagent disk did not reach or stop at the beads mixing position correctly.: Count detection, (mode 5-1,5-2)	
11_01_09	P.Stop/ Stop	R.Disk has moved out of cap op. pos. 11-01-09	The reagent disk moved from the R2 (Cap/Open position) position. It is detected just before cap opener moves. : Count detection, (mode 1-1)	

Alarm Level: The alarm code indicates the severity of the alarm condition. The previous section explains each of these levels in detail.

Alarm Description: This column describes the cause of the alarm condition. Note that there may be more than one cause (description) for a single alarm. Read the entire description before proceeding to remedy the situation.

Remedy: The steps in this column are arranged in sequential order. Perform each step or procedure as it is listed, until the condition is remedied. Note that one remedy (or set of remedies) may apply to several different alarm numbers.

Backup Data Disk

In the Remedy column there are certain instances where you are instructed to power off the analyzer at the circuit breaker due to the nature of the alarm condition. Before you attempt this, ensure that you have a backup data disk available. If you do not have a backup disk available, use the following procedure to create one.

- 1 Obtain a formatted PC-compatible floppy disk. Use a high quality, high density disk.
- 2 Touch **Utility** to access the **UTILITY** screen.
- 3 Touch **Maintenance** to access the **MAINTENANCE** screen.
- 4 Touch **FD Write** to access the **FD WRITE** pop-up window.
- 5 Insert the blank disk into the drive and touch **Start**. The process takes approximately 4 minutes.

3.2 List of Alarms

This is an explanation of the alarm levels (S.Stop / R.Stop, L.Stop, A.Stop / P. Stop, Stop, E. Stop) in the alarm list.

1. S. Stop (Sampling Stop)
Stops rotation of sample disk and aspirating movement of pipetting from sample disk.
(Rack Sampler type: R.Stop (Rack Stop))
2. L.Stop (Line Stop: only Rack sampler type)
Stop the sampler line in the instrument.
3. P. Stop (Partial Stop)
Stops the mechanism that is the cause of the trouble, and the others move generally operation.
(Rack Sampler type: A.Stop (Analyzer Stop))
4. Stop
System removes Stand-by after, it finished movement of all mechanisms in this cycle when happen trouble.
5. E. Stop
Cuts off DC 24 V power supply and all mechanisms stop moving.

Reagent Disk movement

Alarm No.	Level	Alarm message	Alarm Description	Remedy
11_01_01	Stop	R.Disk didn't leave home pos.at reset 11-01-01	The reagent disk did not move out of the home position while the instrument was resetting itself. : Home Position detection, (mode 3-1)	a. Check for proper placement of the reagent cover. b. Perform a system reset from the MAINTENANCE screen. c. If the error recurs, call Technical Support.
11_01_02	Stop	R.Disk didn't reach home pos.at reset 11-01-02	The reagent disk did not reach or stop at the home position while the instrument was resetting itself. : Home Position detection, (mode 3-2)	
11_01_03	Stop	R.Disk didn't reach pos. 1 at reset 11-01-03	The reagent disk did not reach or stop at Position 1 while the instrument was resetting itself. : Count detection, (mode 5-1,5-2)	
11_01_05	P.Stop/ Stop	R.Disk didn't reach home pos.at reset 11-01-05	The reagent disk did not reach or stop at the R2 (Cap/Open position) position correctly. However, this does not apply when the reagent disk rotates from R1 position to R2 position in CCW rotation. : Count detection, (mode 2-1)	a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
11_01_07	P.Stop/ Stop	R. Disk didn't reach mixing pos. properly 11-01-07	The reagent disk did not reach or stop at the beads mixing position correctly.: Count detection, (mode 5-1,5-2)	
11_01_09	P.Stop/ Stop	R.Disk has moved out of cap op. pos. 11-01-09	The reagent disk moved from the R2 (Cap/Open position) position. It is detected just before cap opener moves. : Count detection, (mode 1-1)	

Cap Opener

Alarm No.	Level	Alarm message	Alarm Description	Remedy
12_01_01	Stop	Cap Op didn't leave home pos.at reset 12-01-01	The cap opener did not move out of the F/B home position while the instrument was resetting itself. : F/B Home detection L1, (mode 1-1)	a. Remove the reagent disk cover and check for obstructions. b. Verify the reagent packs are seated properly in the reagent disk. c. Perform a system reset from the MAINTENANCE screen. d. If the error recurs, call Technical Support.
12_01_02	Stop	Cap Op didn't reach home pos.at reset 12-01-02	The cap opener did not reach or stop at the F/B home position while the instrument was resetting itself. : F/B Home detection L1, (mode 2-1)	
12_01_03	Stop	Cap Op. didn't leave cap(out)pos at reset 12-01-03	The cap opener did not move out of the F/B capping position while the instrument was resetting itself. : F/B position detection L2, (mode 1-1)	
12_01_04	Stop	Cap Op. didn't reach cap(out)pos at reset 12-01-04	The cap opener did not reach or stop at the F/B capping position correctly while the instrument was resetting itself. : F/B position detection L2, (mode 2-1)	

Alarm No.	Level	Alarm message	Alarm Description	Remedy
12_01_05	P.Stop/ Stop	Cap Op. didn't reach home or cap(out)pos 12-01-05	The cap opener did not reach or stop at either the F/B home position or the F/B capping position. : F/B Home detection L1 or F/B position detection L2, (mode 2-1)	a. When the analyzer returns to Stand-by, remove the reagent disk cover and check for obstructions. b. Verify the reagent packs are seated properly in the reagent disk. c. Perform a system reset from the MAINTENANCE screen. d. If the error recurs, call Technical Support.
12_01_06	P.Stop/ Stop	Cap Op. didn't reach at in/out home pos 12-01-06	The cap opener did not reach or stop at the F/B home position. : F/B Home detection L1, (mode 5-1,5-2)	
12_01_07	P.Stop/ Stop	Cap Op. didn't reach in/out cap(out)pos 12-01-07	The cap opener did not reach or stop at the F/B capping position. : F/B position detection L2, (mode 5-1,5-2)	
12_01_08	P.Stop/ Stop	Cap Op. didn't reach op.(out)pos. prop. 12-01-08	The cap opener did not reach or stop at the F/B Opening/Closing position. : F/B Home detection L1, (mode 1-1)	
12_01_09	P.Stop/ Stop	Cap Op. didn't reach op.(out)pos. prop. 12-01-09	The cap opener did not reach or stop at the F/B Opening/Closing position. : F/B position detection L2, (mode 1-1)	

Alarm No.	Level	Alarm message	Alarm Description	Remedy
12_02_01	Stop	Cap Op. didn't leave rot.home pos.at reset 12-02-01	The cap opener did not move out of the rotational home position while the instrument was resetting itself. : U/D Home detection L3, (mode 1-1)	a. Perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
12_02_02	Stop	Cap Op. didn't reach rot.home pos at reset 12-02-02	The cap opener did not reach or stop at the rotational home position while the instrument was resetting itself. : U/D Home detection L3, (mode 2-1)	
12_02_03	P.Stop/ Stop	Cap Op. didn't reach rot. home(open)pos 12-02-03	The cap opener did not reach or stop at the rotational home position. : U/D Home detection L3, (mode 5-1, 5-2)	a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
12_02_05	P.Stop/ Stop	Cap Op. didn't reach at rot. close pos. 12-02-05	The cap opener did not reach or stop at the rotational closing position. : U/D Home detection L3, (mode 1-1)	
12_02_06	P.Stop/ Stop	Cap Op. didn't reach rot. capping pos. 12-02-06	The cap opener did not reach or stop at the rotational capping position. : U/D Home detection L3, (mode 1-1)	
12_02_07	P.Stop/ Stop	Cap Op. didn't leave rot. home(open)pos. 12-02-07	The cap opener moved out of the rotational home position. : U/D Home detection L3, (mode 2-1)	

Microparticle Mixer

Alarm No.	Level	Alarm message	Alarm Description	Remedy
13_01_01	Stop	Mixer didn't leave rot.home pos.at reset 13-01-01	The beads mixer did not move out of the rotational home position while the instrument was resetting itself. : Home Position (Washing Pos.) detection P2, (mode 1-1)	a. Perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
13_01_02	Stop	Mixer didn't reach rot.home pos. at reset 13-01-02	The beads mixer did not reach or stop at the rotational home position while the instrument was resetting itself. : Home Position (Washing Pos.) detection P2, (mode 2-1)	a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
13_01_03	P.Stop/ Stop	Mixer didn't reach rot.home(rinse)pos. 13-01-03	The beads mixer did not reach or stop at the rotational home position. : Home Position (Washing Pos.) detection P2, (mode 5-1,5-2)	
13_01_04	P.Stop/ Stop	Mixer didn't reach rot. mixing pos 13-01-04	The beads mixer did not reach or stop at the rotational mixing position. : Mixing Position detection P3, (mode 5-1,5-2)	
13_01_05	P.Stop/ Stop	Mixer move out rot.home pos.at start mix 13-01-05	The beads mixer moved out of the rotational home position when mixing started. : Home Position (Washing Pos.) detection P2, (mode 2-1)	

Alarm No.	Level	Alarm message	Alarm Description	Remedy
13_02_01	Stop	Mixer didn't leave vert.home(up)pos.at res 13-02-01	The beads mixer did not move out of the vertical home position while the instrument was resetting itself. : Home Position detection P1, (mode 1-1)	a. Check for obstructions. b. Perform a system reset from the MAINTENANCE screen. c. If the error recurs, call Technical Support.
13_02_02	Stop	Mixer didn't reach vert.home(up)pos.at res 13-02-02	The beads mixer did not reach or stop at the vertical home position while the instrument was resetting itself. : Home Position detection P1, (mode 2-1)	
13_02_03	P.Stop/ Stop	Mixer didn't reach vertical home(up)pos. 13-02-03	The beads mixer did not reach or stop at the vertical home position. : Home Position detection P1, (mode 5-1,5-2)	a. Check for obstructions. b. When the analyzer returns to Stand-by, switch the analyzer off at the operation switch. Move the mixer up and away from the reagent disk. ! Power must be off to move analyzer components. If power is on, the motors are engaged and attempted movement may damage these components. c. Remove the reagent disk cover and check for obstructions. d. Return the reagent disk cover and switch the analyzer on. The analyzer performs the start-up reset ope- ration and each mechanism returns to its home or Stand-by position. e. If the error recurs, call Technical Support.
13_02_04	P.Stop/ Stop	Mixer didn't reach or stop vert. hom pos 13-02-04	The beads mixer did not reach or stop at the vertical mixing position or at the vertical washing position other than in home position. : Home Position detection P1, (mode 1-1)	
13_02_05	P.Stop/ Stop	Mixer didn't leave vertical home(up)pos 13-02-05	The beads mixer moved out of the vertical home position. : Home Position detection P1	

Barcode Reader

Alarm No.	Level	Alarm message	Alarm Description	Remedy
14_01_01	P.Stop/ Stop	BCR didn't leave home pos. at reset 14-01-01	The bar-code reader did not move out of the home position (R. disk) while the instrument was resetting itself. : Home Position detection, (mode 1-1)	a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
14_01_02	P.Stop/ Stop	BCR didn't reach home pos. at reset 14-01-02	The bar-code reader did not reach or stop at the home position (R. disk) while the instrument was resetting itself. : Home Position detection, (mode 2-1)	
14_01_03	Stop	BCR didn't reach or stop at home pos. 14-01-03	The bar-code reader did not reach or stop at the home position (R. disk). : Home Position detection, (mode 5-1, 5-2)	
14_01_04	P.Stop/ Stop	BCR didn't reach S.Disk read pos. 14-01-04	The bar-code reader did not reach or stop at the reading position (other than home position). : Home Position detection, (mode 1-1)	

Sample Disk: [These alarms are Disk Type only]

Alarm No.	Level	Alarm message	Alarm Description	Remedy
15_01_01	Stop	S.Disk didn't move from home pos at reset 15-01-01	The sample disk did not move out of the home position while the instrument was resetting itself. : Home Position detection, (mode 3-1)	a. Perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
15_01_02	Stop	S.Disk didn't reach home pos at reset 15-01-02	The sample disk did not reach or stop at the home position while the instrument was resetting itself. : Home Position detection, (mode 3-2)	
15_01_03	Stop	S.Disk didn't reach pos.1 at reset 15-01-03	The sample disk did not reach or stop at Position 1 while the instrument was resetting itself. : Count detection, (mode 5-1,5-2)	
15_01_04	P.Stop/ Stop	S.Disk didn't reach sample position 15-01-04	The sample disk did not reach or stop at the sampling position correctly. : Count detection, (mode 6-1,6-2,6-3)	a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
15_01_05	P.Stop/ Stop	S.Disk didn't stop at BC read position 15-01-05	The sample disk did not stop at the barcode reading position correctly.	
15_01_06	P.Stop/ Stop	S.Disk moved from s.pos. while pipetting 15-01-06	The sample disk moved out of the sampling position while sampling was being performed. : Count detection, (mode 2-1)	

S/R arm

Alarm No.	Level	Alarm message	Alarm Description	Remedy
16_01_01	Stop	S/R arm didn't leave home pos. at reset 16-01-01	The pipetter did not move out of the horizontal home position while the instrument was resetting itself. : X Home detection P1	a. Verify the sample protector is down. b. Perform a system reset from the MAINTENANCE screen. c. If the error recurs, call Technical Support
16_01_02	Stop	S/R arm didn't reach home pos. at reset 16-01-02	The pipetter did not reach or stop at the horizontal home position while the instrument was resetting itself. : X Home detection P1	
16_01_03	PStop	S/R arm didn't reach horiz. home pos. 16-01-03	The pipetter did not reach or stop at the horizontal home Position. : X Home detection P1	a. Verify the sample protector is down. b. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. c. If the error recurs, call Technical Support
16_01_04	PStop	S/R arm didn't leave home pos to tip eject 16-01-04	The pipetter did not move out of the home position when pipetter moved to the horizontal tip waste position. : X Home P1 & Sampling P2 detection,	
16_01_05	PStop	S/R arm didn't leave home pos to pip stat. 16-01-05	The pipetter did not move out of the home position when pipetter moved to the horizontal cup position. : X Home P1 & Sampling P2 detection,	
16_01_06	PStop	S/R arm didn't leave home pos.to pos.4 16-01-06	The pipetter did not move out of the S position when pipetter moved to the horizontal DS2 position. : X Home P1 & Sampling P2 detection,	

Alarm No.	Level	Alarm message	Alarm Description	Remedy
16_01_07	P.Stop	S/R arm didn't leave home pos.to pos.3 16-01-07	The pipetter did not move out of S position when pipetter moved to the horizontal DS1 position. : X Home P1 & Sampling P2 detection,	a. Verify the sample protector is down. b. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. c. If the error recurs, call Technical Support.
16_01_14	P.Stop	S/R arm didn't reach horizont. sample pos. 16-01-14	The pipetter did not reach or stop at the horizontal sample position. : X Home P1 & Sampling P2 detection	
16_02_02	Stop	S/R arm didn't reach vert.home pos.at res 16-02-02	The pipetter did not reach or stop at the vertical home position while the instrument was resetting itself. : Z Home detection P4	a. Perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
16_02_03	P.Stop	S/R arm didn't reach vertical home pos. 16-02-03	The pipetter did not reach or stop at the vertical home position. : Z Home detection P4	a. Check for obstacles at the sampling position. b. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. c. If the error recurs, call Technical Support.
16_02_04	P.Stop	S/R arm didn't lower 16-02-04	The pipetter did not move downwards. : Z Home detection P4	
16_02_05	P.Stop	S/R arm detect abnorm desc. exc.saml.pos 16-02-05	The pipetter detected abnormal descent when moving downwards. : Abnormal Descent detection P5	
16_02_06	P.Stop	S/R arm detected an abnormal ascent 16-02-06	The pipetter detected abnormal descent when moving upwards. : Z Home detection P4	

Alarm No.	Level	Alarm message	Alarm Description	Remedy
16_02_07	P.Stop	S/R arm moved out of vertical home pos. 16-02-07	The pipetter moved out of the vertical home position when pipetter moved horizontally. : Z Home detection P4	a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
16_02_08	L.Stop& P.Stop/ Stop	S/R didn't reach vert.home pos.at sa. pos 16-02-08	The pipetter did not reach or stop at the vertical home position at the sample position. : Z Home detection P4	
16_02_09	Stop	S/R arm detected abn. desc. at sample pos.16-02-09	The pipetter detected abnormal descent when moving downwards at the sample position. : Abnormal Descent detection P5	a. Check for obstacles at the sampling position. b. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. c. If the error recurs, call Technical Support.

S/R pipettor

Alarm No.	Level	Alarm message	Alarm Description	Remedy
17_01_01	Stop	S/R pipettor didn't leave home pos.at res 17-01-01	The pipettor syringe did not move out of the home position while the instrument was resetting itself. : Home detection, (mode 1-1)	a. Perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
17_01_02	Stop	S/R pipettor didn't reach home pos.at res 17-01-02	The pipettor syringe did not reach or stop at the home position while the instrument was resetting itself. : Home detection, (mode 2-1)	
17_01_03	P.Stop/ Stop	S/R pipettor didn't reach home pos. 17-01-03	The pipettor syringe did not reach or stop at the home position. : Home detection, (mode 5-1,5-2)	a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
17_01_05	P.Stop/ Stop	S/R pipettor didn't leave home pos. 17-01-05	The pipettor syringe did not move out of the home position. : Home detection, (mode 1-1)	

Gripper

Alarm No.	Level	Alarm message	Alarm Description	Remedy
18_01_01	Stop	Gripper didn't leave X home pos. at reset 18-01-01	The gripper did not move out of the X horizontal home position while the instrument was resetting itself. : X Home Position detection P1, (mode 1-1)	a. Check for obstructions. b. Perform a system reset from the MAINTENANCE screen. c. If the error recurs, call Technical Support.
18_01_02	Stop	Gripper didn't reach X home pos. at reset 18-01-02	The gripper did not reach or stop at the X horizontal home position while the instrument was resetting itself. : X Home Position detection P1, (mode 2-1)	
18_01_03	P.Stop	Gripper didn't reach X home pos. 18-01-03	The gripper did not reach the X horizontal home position during removal as follows; INC→RP, V→RP, DS1→RP, DS2→RP, P1→RP, P2→RP, SW→RP : X Home Position detection P1, (mode 5-1,5-2)	a. Check for obstructions. b. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen c. If the error recurs, call Technical Support.
18_01_04	P.Stop	Gripper didn't leave X home pos. 18-01-04	The gripper moved out of the X horizontal home position during removal as follows; RP→VC, RP→TC(partly), RP→INC, RP→V, RP→DS1, RP→DS2, RP→P1, RP→SW : X Home Position detection P1, (mode 1-1)	

Alarm No.	Level	Alarm message	Alarm Description	Remedy
18_01_05	P.Stop	Gripper left X home position 18-01-05	The gripper moved out of the X horizontal home position during removal between 4•points;HP, SP, RP, STP. : X Home Position detection P1, (mode 2-1)	a. Check for obstructions. b. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen c. If the error recurs, call Technical Support.
18_01_10	P.Stop	Gripper left X home pos. from reset pos 18-01-10	The gripper moved out of the X horizontal home position. : X Home Position detection P1, (mode 2-1)	
18_02_01	Stop	Gripper didn't leave Y home pos. at reset 18-02-01	The gripper did not move out of the Y horizontal home position while the instrument was resetting itself. : Y Home Position detection P3, (mode 1-1)	a. Perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
18_02_02	Stop	Gripper didn't reach Y home pos. at reset 18-02-02	The gripper did not reach or stop at the Y horizontal home position while the instrument was resetting itself. : Y Home Position detection P3, (mode 2-1)	
18_02_04	Stop	Gripper didn't leave Y home pos. at reset 18-02-04	The gripper did not move out of the Y horizontal home position while the instrument was resetting itself, and during removal as follows;HP→RP : Y Home Position detection P3, (mode 1-1)	

Alarm No.	Level	Alarm message	Alarm Description	Remedy
18_02_09	P.Stop	Gripper didn't reach Y reset pos. 18-02-09	The gripper did not reach or stop at the Y horizontal reset position during removal as follows: TP→RP, SIP→RP, INC→RP, V→RP, DS1→RP, DS2→RP, P1→RP, P2→RP, SW→RP, : Y Reset position detection P5, (mode 5-1,5-2)	a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
18_02_10	P.Stop	Gripper didn't leave Y reset pos. 18-02-10	The gripper did not move out of the Y horizontal reset position during removal as follows: RP→SP, RP→STP, RP→VC, RP→TC, RP→SIP, RP→INC, RP→V, RP→DS1, RP→DS2, RP→P1, RP→SW : Y Reset Position detection P5, (mode 1-1)	
18_02_13	P.Stop	Gripper leaves Y reset pos. from reset pos 18-02-13	The gripper moved out of the Y horizontal reset position. : Y Reset Position detection P5, (mode 2-1)	
18_03_02	Stop	Gripper didn't reach vert.home pos.at res 18-03-02	The gripper did not reach or stop at the vertical home position while the instrument was resetting itself. : Z Home Position detection P6, (mode 2-1)	a. Perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
18_03_03	P.Stop	Gripper didn't reach vertical home pos. 18-03-03	The gripper did not reach or stop at the vertical home position. : Z Home Position detection P6, (mode 5-*1,5-2)	a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.

Alarm No.	Level	Alarm message	Alarm Description	Remedy
18_03_04	P.Stop	Gripper didn't leave vertical home pos. 18-03-04	The gripper did not move downwards. : Z Home Position detection P6, (mode 1-1)	a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
18_03_05	W	Gripper detected abnormal descent 18-03-05	The gripper detected an abnormal status when moving downwards. : Abnormal Status detection P7, (mode 7-1)	a. Verify there are no obstructions on the tip and cup trays. b. If the error recurs, call Technical Support.
18_03_06	P.Stop	Gripper left vert.home pos.at X-Ymovement 18-03-06	The gripper moved out of the vertical home position.The error applies to all X-Y movements when gripper just moves from the HP, SP, RP, or STP. : Z Home Position detection P6, (mode 2-1)	a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
18_04_01	P.Stop	Gripper finger didn't close 18-04-01	The gripper finger did not close. : Gripper finger detection P8, (mode 2-1)	a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
18_04_02	P.Stop	Gripper finger didn't open 18-04-02	The gripper finger did not open. : Gripper finger detection P8, (mode 1-1)	
18_04_03	P.Stop	Gripper finger didn't find a tip 18-04-03	The gripper finger did not find a tip. : Gripper finger detection P8, (mode 1-1)	
18_04_05	P.Stop	Gripper finger didn't find a cup 18-04-05	The gripper finger found no cup. : Gripper finger detection P8, (mode 1-1)	

Alarm No.	Level	Alarm message	Alarm Description	Remedy
18_05_01	P.Stop/ Stop	Gripper couldn't pickup in pipett.station 18-05-01	Cup pick up failed (VB). The gripper did not get a cup at VB position. P.Stop: If the alarm takes place during operation. Stop: If the alarm takes place out of operation.	a. Check for spills on the incubator and clean, if necessary. b. Repeat any tests that were excluded. c. If the error recurs, call Technical Support.
18_05_02	W	Gripper didn't pickup in incubator 18-05-02	Cup pick up failed (INC to VB). The gripper did not get a cup at incubator position before it would carry the cup to VB position when operation.	
18_05_03	Stop	Gripper didn't pickup in incub.to pip.st. 18-05-03	Cup pick up failed (INC to VB). The gripper did not get a cup at incubator position before it would carry the cup to VB position when T/M.	
18_05_04	W	Gripper didn't pickup a cup in incub. 18-05-04	Cup pick up failed (IND to SIP). The gripper did not get a cup at incubator position before it would carry the cup to VB position when operation.	
18_05_05	Stop	Gripper didn't pickup in incub.to asp.st. 18-05-05	Cup pick up failed (INC to SIP). The gripper did not get a cup at incubator position before it would carry the cup to VB position when T/M.	

Alarm No.	Level	Alarm message	Alarm Description	Remedy
18_05_06	P.Stop/ Stop	Gripper couldn't pick up in asp.st. 18-05-06	Cup pick up failed (SIP). The gripper did not get a cup at sipping position P.Stop: If the alarm takes place during operation. Stop: If the alarm takes place out of operation.	<ol style="list-style-type: none"> Check for spills on the incubator and clean, if necessary. Repeat any tests that were excluded. If the error recurs, call Technical Support.



INC: Incubator pos.
P1: Tip pos.1 on Buffer
TC: Tip magazine
STP: stand-by pos.
V: Cup pos.1 on Buffer
P2: Tip pos.2 on Buffer
VC: Cup magazine
SIP: Sipping pos.
DS1: Dilution pos. 1 on Buffer
SW: Solid Waste pos.
HP: Home pos.
DS2: Dilution pos. 2 on Buffer
RP: Rest pos.
SP: Shunt pos.

Solid Waste

Alarm No.	Level	Alarm message	Alarm Description	Remedy
19_01_01	Stop	Solid waste tray didn't leave home pos. 19-01-01	The solid waste mechanism did not move out of the home position while the instrument was resetting itself. : Home Position detection, (mode 3-1)	a. Check for stray cups or tips behind the solid waste tray and remove, if necessary. b. Perform a system reset from the MAINTENANCE screen. c. If the error recurs, call Technical Support.
19_01_02	Stop	Solid waste tray didn't reach home pos. 19-01-02	The solid waste mechanism did not reach or stop at the home position while the instrument was resetting itself. : Home Position detection, (mode 3-2)	
19_01_03	P.Stop/ Stop	Solid waste tray didn't reach home pos. 19-01-03	The solid waste mechanism did not reach or stop at the home position. : Home Position detection, (mode 6-1,6-2,6-3)	a. Check for stray cups or tips behind the solid waste tray and remove, if necessary. b. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. c. If the error recurs, call Technical Support.

Sipper arm

Alarm No.	Level	Alarm message	Alarm Description	Remedy
20_01_01	Stop	Sipper arm didn't leave hor.home pos reset20-01-01	The sipper did not move out of the horizontal end position while the instrument was resetting itself. : X home detection P1, (mode 1-1)	a. Perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
20_01_02	Stop	Sipper arm didn't stop at home pos. reset 20-01-02	The sipper did not reach or stop at the horizontal end position while the instrument was resetting itself. : X home detection P1, (mode 2-1)	
20_01_03	P.Stop/ Stop	Sipper arm didn't reach at hori.home pos 20-01-03	The sipper did not reach or stop at the horizontal home position. : X home detection P1, (mode 5-1,5-2)	a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
20_01_07	P.Stop/ Stop	Sipper arm didn't leave home or asp.pos 20-01-07	The sipper did not move out of the home position or SIP position when moving to horizontal WA position. : X home position detection P1 or X end detection position P2, (mode 1-1)	
20_01_08	P.Stop/ Stop	Sipper arm didn't reach horiz. asp. pos 20-01-08	The sipper did not reach or stop at the horizontal SIP position. : X end (SIP) position detection P2, (mode 5-1,5-2)	
20_02_02	Stop	Sipper arm didn't reach vert.home pos.res 20-02-02	The sipper did not reach or stop at the vertical home position while the instrument was resetting itself. : Z home detection P4, (mode 2-1)	a. Verify the ProCell/CleanCell lids are open. b. Perform a system reset from the MAINTENANCE screen. c. If the error recurs, call Technical Support.

Alarm No.	Level	Alarm message	Alarm Description	Remedy
20_02_03	P.Stop/ Stop	Sipper arm didn't reach vert.home pos.res 20-02-03	The sipper did not reach or stop at the vertical home position. : Z home detection P4, (mode 5-1,5-2)	a. Verify the ProCell/CleanCell lids are open. b. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. c. If the error recurs, call Technical Support.
20_02_04	P.Stop/ Stop	Sipper arm didn't lower 20-02-04	The sipper did not move downwards. : Z home detection P4, (mode 1-1)	
20_02_05	P.Stop/ Stop	Sipper arm detected abnormal descent 20-02-05	The sipper detected an abnormal status when moving downwards. : Abnormal detection P5, (mode 7-1)	
20_02_06	P.Stop	Sipper arm detected abnormal ascent 20-02-06	The sipper detected an abnormal status when moving upwards. : Z home detection P4, (mode 1-1)	
20_02_07	P.Stop/ Stop	Sipper arm left v.home pos. to move horiz 20-02-07	The sipper moved out of the vertical home position when it moved in a horizontal direction. : Z home detection P4, (mode 2-1)	

Sipper pipettor

Alarm No.	Level	Alarm message	Alarm Description	Remedy
21_01_01	Stop	Sipper pipet.didn't leave home pos. reset 21-01-01	The sipper syringe did not move out of the home position while the instrument was resetting itself. : Home detection, (mode 1-1)	a. Perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
21_01_02	Stop	Sipper pipet.didn't reach home pos. reset 21-01-02	The sipper syringe did not reach or stop at the home position while the instrument was resetting itself. : Home detection, (mode 2-1)	
21_01_03	P.Stop/ Stop	Sipper pipettor didn't reach home pos. 21-01-03	The sipper syringe did not reach or stop at the home position. : Home detection, (mode 5-1,5-2)	a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
21_01_05	P.Stop/ Stop	Sipper pipettor didn't leave home pos. 21-01-05	The sipper syringe did not move out of the home position . : Home detection, (mode 1-1)	

Magnet Drive

Alarm No.	Level	Alarm message	Alarm Description	Remedy
22_01_01	Stop	Magnet didn't leave home pos. at a reset 22-01-01	The magnet did not move out of the home position while the instrument was resetting itself. : Home detection, (mode 1-1)	a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
22_01_02	Stop	Magnet didn't reach home pos. at a reset 22-01-02	The magnet did not reach or stop at the home position while the instrument was resetting itself. : Home detection, (mode 2-1)	
22_01_03	Stop	Magnet didn't reach home pos. 22-01-03	The magnet did not reach or stop at the home position. : Home detection, (mode 5-1,5-2)	
22_01_04	Stop	Magnet didn't leave home pos. 22-01-04	The magnet did not move out of the home position. : Home detection, (mode 1-1)	

Pipetting station

Alarm No.	Level	Alarm message	Alarm Description	Remedy
23_01_01	P.Stop/ Stop	Cup pos. 5 in Pip.Station was not empty 23-01-01	A cup was detected at the V position on the buffer station when gripper put a cup into the V position.	a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. b. Check if there are cups in the pipetting station. c. If there are no cups in the pipetting station, clean the pipetting station with a cotton swab. d. If the error recurs, call Technical Support.
23_01_02	P.Stop/ Stop	No cup detected at pos.5 in pip.Station 23-01-02	A cup was not detected at the V position on the buffer station.	
23_01_03	P.Stop/ Stop	Cup pos. 3 in Pip.St. was not empty 23-01-03	A cup was detected at the DS1 position on the buffer station when gripper put a cup into the DS1 position.	
23_01_04	P.Stop/ Stop	No cup detected at pos.3 in pip.Station 23-01-04	A cup was not detected at the DS1 position on the buffer station.	
23_01_05	P.Stop/ Stop	Cup pos. 4 in Pip.St. was not empty 23-01-05	A cup was detected at the DS2 position on the buffer station when gripper put a cup into the DS2 position.	
23_01_06	P.Stop/ Stop	No cup detected at pos. 4 in pip.station 23-01-06	A cup was not detected at the DS2 position on the buffer station.	
23_01_07	P.Stop/ Stop	Tip pos.1 in Pip.St. was not empty 23-01-07	A tip was detected at the P1 position on the buffer station when gripper put a tip into the P1 position. : Present/Absent detection TB1, (mode 1-1)	a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. b. Check if there are tips in the pipetting station. c. If there are no tips in the pipetting station, clean the pipetting station with a cotton swab. d. If the error recurs, call Technical Support.
23_01_08	P.Stop/ Stop	No tip detected at pos.1 in pip.station 23-01-08	A tip was not detected at the P1 position on the buffer station. : Present/Absent detection TB1, (mode 2-1)	

Alarm No.	Level	Alarm message	Alarm Description	Remedy
23_01_09	P.Stop/ Stop	Tip pos.2 in Pip.St. was not empty 23-01-09	A tip was detected at the P2 position on the buffer station when gripper put a tip into the P2 position. : Present/Absent detection TB2, (mode 1-1)	a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. b. Check if there are tips in the pipetting station. c. If there are no tips in the pipetting station, clean the pipetting station with a cotton swab. d. If the error recurs, call Technical Support.
23_01_10	P.Stop/ Stop	No tip detected at pos. 2 in pip.station 23-01-10	A tip was not detected at the P2 position on the buffer station. : Present/Absent detection TB2, (mode 2-1)	

Liquid waste

Alarm No.	Level	Alarm message	Alarm Description	Remedy
24_01_01	P.Stop	Liquid waste container is full 24-01-01	The liquid waste tank is full. : Liquid waste detection, (mode 1-1)	a. Empty the container. b. If the container is not full, call Technical Support
24_02_01	E.Stop	Liquid waste container is missing 24-02-01	There is no liquid waste tank. : Liquid waste tank detection, (mode 1-1)	a. Replace the liquid waste container. b. If the container is in place, call Technical Support.

System water

Alarm No.	Level	Alarm message	Alarm Description	Remedy
25_01_01	P.Stop	System water container is low or empty 25-01-01	The level of the system water goes down and is short. : System water level detection float SW, (mode 1-1)	a. Refill the distilled water container. b. If the container is full, call Technical Support.

Solid waste

Alarm No.	Level	Alarm message	Alarm Description	Remedy
26_01_01	E.Stop	Solid waste tray is missing 26-01-01	There is no solid waste box. : Solid waste box detection, (mode 1-1)	a. Replace the solid waste tray. Ensure the tray is properly installed. b. If the tray is in place, call Technical Support.
26_02_01	P.Stop	Solid waste tray is full 26-02-01	The solid waste box is full. (There are more than 650 tips and cups in the solid waste box.)	Discard the full Clean-Liner properly and install a new Clean-Liner.

Reagent disk cover

Alarm No.	Level	Alarm message	Alarm Description	Remedy
28_01_01	W	Reagent disk cover is open 28-01-01	The cover of the reagent disk is open.	a. Return the cover to the reagent disk. b. If the cover is in place, call Technical Support.

GP Controller

Alarm No.	Level	Alarm message	Alarm Description	Remedy
29_01_01	E.Stop	Control err.signal for S.Disk rot. detec 29-01-01	Controller error signal for the sample disk rotation is detected. : GPCONT1	<p>There is potentially an electronic problem.</p> <p>a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen.</p> <p>b. Power the analyzer OFF at the circuit breaker, then ON. Before performing this step, refer to the Backup Data Disk heading on p. 3-7.</p> <p>c. If the error recurs, call Technical Support.</p>
29_01_02	E.Stop	Control err.signal for R.Disk rot.detec 29-01-02	Controller error signal for the reagent disk rotation is detected. : GPCONT1	
29_01_03	E.Stop	Contr.err.sig. cap open in/out movement 29-01-03	Controller error signal for the cap opener F/B movement is detected. : GPCONT2	
29_01_04	E.Stop	Contr.err.signal for cap op./cl.movement 29-01-04	Controller error signal for the cap opener open/close movement is detected. : GPCONT2	
29_01_05	E.Stop	Contr.err.sig. for mixer horiz.movement. 29-01-05	Controller error signal for the beads mixing arm rotation is detected. : GPCONT3	
29_01_06	E.Stop	Contr.err.sig.for mixer up/down movement 29-01-06	Controller error signal for the beads mixing up/down movement is detected. : GPCONT3	
29_01_07	E.Stop	Contr.err.sig.for waste tray mov.detec. 29-01-07	Controller error signal for the solid waste movement is detected. : GPCONT4	
29_01_08	E.Stop	Control err.signal for BCR rot.detected 29-01-08	Controller error signal for the bar code reader rotation is detected. : GPCONT4	

Alarm No.	Level	Alarm message	Alarm Description	Remedy
29_01_09	E.Stop	Contr.err.sig. for S/R arm Xmov.detected 29-01-09	Controller error signal for the pipetter X movement is detected. : GPCONT5	<p>There is potentially an electronic problem.</p> <p>a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen.</p> <p>b. Power the analyzer OFF at the circuit breaker, then ON. Before performing this step, refer to the Backup Data Disk heading on p. 3-7.</p> <p>c. If the error recurs, call Technical Support.</p>
29_01_10	E.Stop	Contr.err.sig. for S/R arm Zmov.detected 29-01-10	Controller error signal for the pipetter Z movement is detected. : GPCONT5	
29_01_11	E.Stop	Contr.err.sig.for sipper arm Xmov.detect. 29-01-11	Controller error signal for the sipper X movement is detected. : GPCONT6	
29_01_12	E.Stop	Contr.err.sig.for sipper arm Zmov.detect. 29-01-12	Controller error signal of the sipper Z movement is detected. : GPCONT6	
29_01_13	E.Stop	Contr.err.sig.for gripper Xmov. detected 29-01-13	Controller error signal for the gripper X movement is detected. : GPCONT7	
29_01_14	E.Stop	Contr.err.sig.for gripper Z mov. detected 29-01-14	Controller error signal for the gripper Z movement is detected. : GPCONT7	
29_01_15	E.Stop	Contr.err.sig.for gripper Ymov. detected 29-01-15	Controller error signal for the gripper Y movement is detected. : GPCONT8	
29_01_16	E.Stop	Contr.err.sig. for magnet drive movement 29-01-16	Controller error signal for the magnet movement inside the detection unit is detected. : GPCONT8	

Alarm No.	Level	Alarm message	Alarm Description	Remedy
29_01_17	E.Stop	Contr.err.sig. for S/R pip.mov. detected 29-01-17	Controller error signal for the pipetter syringe movement is detected. : GPCONT9	<p>There is potentially an electronic problem.</p> <p>a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen.</p> <p>b. Power the analyzer OFF at the circuit breaker, then ON. Before performing this step, refer to the Backup Data Disk heading on p. 3-7.</p> <p>c. If the error recurs, call Technical Support.</p>
29_01_18	E.Stop	Contr.err.signal for sipper pip.movement 29-01-18	Controller error signal for the sipper syringe movement is detected. : GPCONT9	
29_01_19	E.Stop	Control err. signal 29-01-19	GPCONT10	
29_01_20	E.Stop	Control err. signal 29-01-20	GPCONT10	

Rack GP Controller

Alarm No.	Level	Alarm message	Alarm Description	Remedy
29_01_21	E.S	Control err. signal 29-01-21	Abnormal motor controller detected. (Motor No. 21: GPCONT)	<p>There is potentially an electronic problem.</p> <p>a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen.</p> <p>b. Power the analyzer OFF at the circuit breaker, then ON. Before performing this step, refer to the Backup Data Disk heading on p. 3-7.</p> <p>c. If the error recurs, call Technical Support.</p>
29_01_22	E.S	Control err. signal 29-01-22	Abnormal motor controller detected.(Motor No. 22: GPCONT)	
29_01_23	E.S	Control err. signal 29-01-23	Abnormal motor controller detected. (Motor No. 23: GPCONT)	
29_01_24	E.S	Control err. signal 29-01-24	Abnormal motor controller detected. (Motor No. 24: GPCONT)	
29_01_25	E.S	Control err. signal 29-01-25	Abnormal motor controller detected. (Motor No. 25: GPCONT)	
29_01_26	E.S	Control err. signal 29-01-26	Abnormal motor controller detected. (Motor No. 26: GPCONT)	
29_01_27	E.S	Control err. signal 29-01-27	Abnormal motor controller detected. (Motor No. 27: GPCONT)	
29_01_28	E.S	Control err. signal 29-01-28	Abnormal motor controller detected. (Motor No. 28: GPCONT)	
29_01_29	E.S	Control err. signal 29-01-29	Abnormal motor controller detected. (Motor No. 29: GPCONT)	
29_01_30	E.S	Control err. signal 29-01-30	Abnormal motor controller detected. (Motor No. 30: GPCONT)	
29_01_31	E.S	Rack GP controller 29-01-31	Abnormal motor controller detected. (Motor No. 31: GPCONT)	
29_01_32	E.S	Rack GP controller 29-01-32	Abnormal motor controller detected. (Motor No. 32: GPCONT)	

Alarm No.	Level	Alarm message	Alarm Description	Remedy
29_01_33	E.S	Rack GP controller 29-01-33	Abnormal motor controller detected. (Motor No. 33: GPCONT)	<p>There is potentially an electronic problem.</p> <p>a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen.</p> <p>b. Power the analyzer OFF at the circuit breaker, then ON. Before performing this step, refer to the Backup Data Disk heading on p. 3-7.</p> <p>c. If the error recurs, call Technical Support.</p>
29_01_34	E.S	Rack GP controller 29-01-34	Abnormal motor controller detected. (Motor No. 34: GPCONT)	
29_01_35	E.S	Rack GP controller 29-01-35	Abnormal motor controller detected. (Motor No. 35: GPCONT)	
29_01_36	E.S	Rack GP controller 29-01-36	Abnormal motor controller detected. (Motor No. 36: GPCONT)	
29_01_37	E.S	Rack GP controller 29-01-37	Abnormal motor controller detected. (Motor No. 37: GPCONT)	
29_01_38	E.S	Rack GP controller 29-01-38	Abnormal motor controller detected. (Motor No. 38: GPCONT)	
29_01_39	E.S	Rack GP controller 29-01-39	Abnormal motor controller detected. (Motor No. 39: GPCONT)	
29_01_40	E.S	Rack GP controller 29-01-40	Abnormal motor controller detected. (Motor No. 40: GPCONT)	

GM Controller

Alarm No.	Level	Alarm message	Alarm Description	Remedy
29_02_01	E.Stop	An electronic failure (GMCONT) 29-02-01	Controller error signal for the solenoid valve, HV switching, +24VDC on/off7, etc. is detected. : GMCONT	There is potentially an electronic problem. a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. b. Power the analyzer OFF at the circuit breaker, then ON. Before performing this step, refer to the Backup Data Disk heading on p. 3-7. c. If the error recurs, call Technical Support.



1. The following abbreviations apply to positions on the buffer station.
P1: Tip pos.1, **P2**: Tip pos.2
2. FOR SERVICE ONLY: See the table for GPCONT/GMCONT on the EMOT110 board for details.

GP Controller Timeout

Alarm No.	Level	Alarm message	Alarm Description	Remedy
30-01-01	E.Stop	Timeout error for S.Disk rotation 30-01-01	Timeout of sample disk rotation is detected. : GPCONT1	<p>There is potentially an electronic problem.</p> <p>a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen.</p> <p>b. Power the analyzer OFF at the circuit breaker, then ON. Before performing this step, refer to the Backup Data Disk heading on p. 3-7.</p> <p>c. If the error recurs, call Technical Support.</p>
30-01-02	E.Stop	Timeout error for R.Disk rotation 30-01-02	Timeout of reagent disk rotation is detected. : GPCONT1	
30-01-03	E.Stop	Timeout err. for cap open mech./mov. 30-01-03	Timeout of cap opener F/B movement is detected. : GPCONT2	
30-01-04	E.Stop	Timeout err. for cap op. mech./movement 30-01-04	Timeout of cap opener open/close movement is detected. : GPCONT2	
30-01-05	E.Stop	Timeout err. for mixer horiz. movement 30-01-05	Timeout of beads mixing arm rotation is detected. : GPCONT3	
30-01-06	E.Stop	Timeout err. for mixer up/down movement 30-01-06	Timeout of beads mixing up/down movement is detected. : GPCONT3	
30-01-07	E.Stop	Timeout err. for s. waste tray movement 30-01-07	Timeout of solid waste movement is detected. : GPCONT4	
30-01-08	E.Stop	Timeout error for BCR rotation 30-01-08	Timeout of bar code reader rotation is detected. : GPCONT4	

Alarm No.	Level	Alarm message	Alarm Description	Remedy
30-01-09	E.Stop	Timeout err. for S/R arm X movement 30-01-09	Timeout of pipetter X movement is detected. : GPCONT5	<p>There is potentially an electronic problem.</p> <p>a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen.</p> <p>b. Power the analyzer OFF at the circuit breaker, then ON. Before performing this step, refer to the Backup Data Disk heading on p. 3-7.</p> <p>c. If the error recurs, call Technical Support.</p>
30-01-10	E.Stop	Timeout err. for S/R arm Z movement 30-01-10	Timeout of pipetter Z movement is detected. : GPCONT5	
30-01-11	E.Stop	Timeout err. for sipper arm X movement 30-01-11	Timeout of sipper X movement is detected. : GPCONT6	
30-01-12	E.Stop	Timeout err. for sipper arm Z movement 30-01-12	Timeout of sipper Z movement is detected. : GPCONT6	
30-01-13	E.Stop	Timeout err. for gripper X movement 30-01-13	Timeout of gripper X movement is detected. : GPCONT7	
30-01-14	E.Stop	Timeout err. for gripper Z movement 30-01-14	Timeout of gripper Z movement is detected. : GPCONT7	
30-01-15	E.Stop	Timeout err. for gripper 30-01-15	Timeout of gripper Y movement is detected. : GPCONT8	
30-01-16	E.Stop	Timeout err. for magnet drive movement 30-01-16	Timeout of magnet movement inside the detection unit is detected. : GPCONT8	
30-01-17	E.Stop	Timeout err. for S/R pipetter movement 30-01-17	Timeout of pipetter syringe movement is detected : GPCONT9	

Alarm No.	Level	Alarm message	Alarm Description	Remedy
30-01-18	E.Stop	Timeout err. for sipper pipetter movement 30-01-18	Timeout of sipper syringe movement is detected. (Motor No. 21: GPCONT9)	<p>There is potentially an electronic problem.</p> <ol style="list-style-type: none"> When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. Power the analyzer OFF at the circuit breaker, then ON. Before performing this step, refer to the Backup Data Disk heading on p. 3-7. If the error recurs, call Technical Support.
30-01-19	E.Stop	Control err. signal 30-01-19	GPCONT10	
30-01-20	E.Stop	Control err. signal 30-01-20	GPCONT10	
30_01_21	E.S	Timeout err. 30-01-21	Motor controller time-out detected. (Motor No. 21: GPCONT)	
30_01_22	E.S	Timeout err. 30-01-22	Motor controller time-out detected. (Motor No. 22: GPCONT)	
30_01_23	E.S	Timeout err. 30-01-23	Motor controller time-out detected. (Motor No. 23: GPCONT)	
30_01_24	E.S	Timeout err. 30-01-24	Motor controller time-out detected. (Motor No. 24: GPCONT)	
30_01_25	E.S	Timeout err. 30-01-25	Motor controller time-out detected. (Motor No. 25: GPCONT)	
30_01_26	E.S	Timeout err. 30-01-26	Motor controller time-out detected. (Motor No. 26: GPCONT)	
30_01_27	E.S	Timeout err. 30-01-27	Motor controller time-out detected. (Motor No. 27: GPCONT)	
30_01_28	E.S	Timeout err. 30-01-28	Motor controller time-out detected. (Motor No. 28: GPCONT)	
30_01_29	E.S	Timeout err. 30-01-29	Motor controller time-out detected. (Motor No. 29: GPCONT)	
30_01_30	E.S	Timeout err. 30-01-30	Motor controller time-out detected. (Motor No. 30: GPCONT)	

Rack GP Controller Timeout

Alarm No.	Level	Alarm message	Alarm Description	Remedy
30_01_31	E.S	Rack GP controller timeout 30-01-31	Motor controller time-out detected. (Motor No. 31: GPCONT)	<p>There is potentially an electronic problem.</p> <p>a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen.</p> <p>b. Power the analyzer OFF at the circuit breaker, then ON. Before performing this step, refer to the Backup Data Disk heading on p. 3-7.</p> <p>c. If the error recurs, call Technical Support.</p>
30_01_32	E.S	Rack GP controller timeout 30-01-32	Motor controller time-out detected. (Motor No. 32: GPCONT)	
30_01_33	E.S	Rack GP controller timeout 30-01-33	Motor controller time-out detected. (Motor No. 33: GPCONT)	
30_01_34	E.S	Rack GP controller timeout 30-01-34	Motor controller time-out detected. (Motor No. 34: GPCONT)	
30_01_35	E.S	Rack GP controller timeout 30-01-35	Motor controller time-out detected. (Motor No. 35: GPCONT)	
30_01_36	E.S	Rack GP controller timeout 30-01-36	Motor controller time-out detected. (Motor No. 36: GPCONT)	
30_01_37	E.S	Rack GP controller timeout 30-01-37	Motor controller time-out detected. (Motor No. 37: GPCONT)	
30_01_38	E.S	Rack GP controller timeout 30-01-38	Motor controller time-out detected. (Motor No. 38: GPCONT)	
30_01_39	E.S	Rack GP controller timeout 30-01-39	Motor controller time-out detected. (Motor No. 39: GPCONT)	
30_01_40	E.S	Rack GP controller timeout 30-01-40	Motor controller time-out detected. (Motor No. 40: GPCONT)	

GM Controller Timeout

Alarm No.	Level	Alarm message	Alarm Description	Remedy
30-02-01	E.Stop	An electronic failure (GMCONT) 30-02-01	Timeout of solenoid valve, HV switching, +24VDC on/off, DC power failure, fuse, or temp. control etc. is detected. : GMCONT	There is potentially an electronic problem. a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. b. Power the analyzer OFF at the circuit breaker, then ON. Before performing this step, refer to the Backup Data Disk heading on p. 3-7. c. If the error recurs, call Technical Support.



FOR SERVICE ONLY: See the table for GPCONT/GMCONT on the EMOT100 board for details.

ADC

Alarm No.	Level	Alarm message	Alarm Description	Remedy
31-01-01	W	Abnormal ADC 31-01-01	Abnormal ADC detected.	Call Technical Support.
31-01-02	W	ADC timeout 31-01-02	ADC timeout detected.	
31-01-03	W	Abnormal ADC reference voltage 31-01-03	Abnormal ADC standard voltage detected.	

ProCell

Alarm No.	Level	Alarm message	Alarm Description	Remedy
31-02-01	W	ProCell signal out of range at prep.cycle 31-02-01	Abnormal signal level of ProCell was detected during Pre-operation Cycle (Resume cycle).	a. Check for bubbles or foam in the ProCell bottles. b. Replace current ProCell with a new bottle. Perform a MC Preparation (5 cycles) from the MAINTENANCE screen. c. If the error recurs, call Technical Support.
31-02-02	P.Stop	Abnormal current at measuring cell check 31-02-02	Abnormal current of measuring cell was detected during Pre-operation Cycle (Resume cycle).	
31-02-03	P.Stop	MC current over range at operation 31-02-03	Abnormal current of measuring cell was detected during Sample measurement.	

Power Supply

Alarm No.	Level	Alarm message	Alarm Description	Remedy
33-01-01	Stop	A low +15V (for temperature control) signal 33-01-01	Low signal limit of +15VDC (for temp. control) detected.	<p>There is potentially an electronic problem.</p> <p>a. When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen.</p> <p>b. Power the analyzer OFF at the circuit breaker, then ON. Before performing this step, refer to the Backup Data Disk heading on p. 3-7.</p> <p>c. If the error recurs, call Technical Support.</p>
33-01-02	Stop	A low -15V (for temperature control) signal 33-01-02	Low signal limit of -15VDC (for temp. control) detected.	
33-01-03	Stop	A low + 15V (for analog) signal 33-01-03	Low signal limit of +15VDC (for analog) detected.	
33-01-04	Stop	A low - 15V (for analog) signal 33-01-04	Low signal limit of -15VDC (for analog) detected.	
33-01-05	Stop	A low +12V (for analog) signal 33-01-05	Low signal limit of +12VDC (for analog) detected.	
33-01-06	Stop	A low -12V (for analog) signal 33-01-06	Low signal limit of -12VDC (for analog) detected.	
33-01-07	Stop	A low +12V signal 33-01-07	Low signal limit of +12VDC detected.	
33-01-08	E.Stop	A low +24V signal 33-01-08	Low signal limit of +24VDC detected.	

D01, D02, D03, E10 fuse

Alarm No.	Level	Alarm message	Alarm Description	Remedy
34-01-01	E.Stop	A blown fuse on D01 circuit board 34-01-01	Burnt out fuse detected on the D01 board.	<p>There is potentially an electronic problem.</p> <ol style="list-style-type: none"> When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. Power the analyzer OFF at the circuit breaker, then ON. Before performing this step, refer to the Backup Data Disk heading on p. 3-7. If the error recurs, call Technical Support.
34-01-02	E.Stop	A blown fuse on D02 circuit board 34-01-02	Burnt out fuse detected on the D02 board.	<ol style="list-style-type: none"> Check for stray cups and tips behind the solid waste tray. If any are present, remove and then perform a system reset from the MAINTENANCE screen. Power the analyzer OFF at the circuit breaker, then ON. Before performing this step, refer to the Backup Data Disk heading on p. 3-7. If the error recurs, then there is potentially an electronic problem; call Technical Support.

Alarm No.	Level	Alarm message	Alarm Description	Remedy
34-01-03	E.Stop	A blown fuse on DO3 circuit board 34-01-03	Burnt out fuse detected on the DO3 board.	<p>There is potentially an electronic problem.</p> <ol style="list-style-type: none"> When the analyzer returns to Stand-by, perform a system reset from the MAINTENANCE screen. Power the analyzer OFF at the circuit breaker, then ON. Before performing this step, refer to the Backup Data Disk heading on p. 3-7. If the error recurs, call Technical Support.
34-01-04	E.Stop	A blown fuse on EIO circuit board 34-01-04	Burnt out fuse detected on the EIO board.	

Sample

Alarm No.	Level	Alarm message	Alarm Description	Remedy
35_01_01	W	No sample detected (empty/no tube) 35-01-01	<p>The pipettor does not detect a liquid level at the sample position because the position is not set the sample.</p> <p>Sub-code: Disk Type:Pos.No.1-30 and Test No. Rack Sampler Type: Rack ID, Pos.No.1-5 and Test No.</p>	<ol style="list-style-type: none"> Verify sample placement against worklist. Check sample volume. If the sample volume is adequate, access the VOLTAGE MONITOR screen from the UTILITY screen. If the S/R probe LLD voltage is > 2.00 V, then clean the S/R probe. If the alarm recurs immediately, call Technical Support.

Alarm No.	Level	Alarm message	Alarm Description	Remedy
35_01_02	W	Sample short (insufficient volume) 35-01-02	<p>The pipetter detect a liquid level at the sample position. But the pipetter stays too shallow in the sample to aspirate it in the normal manner because the sample volume is shorter than the dead volume specification.</p> <p>Sub-code: Disk Type:Pos.No.1-30 and Test No. Rack Sampler Type: Rack ID, Pos.No.1-5 and Test No.</p>	<p>a. Check sample volume. b. Check that tubes are properly placed on the sample disk. c. If the sample volume is adequate and tubes are in place, call Technical Support.</p>
35_01_06	W	Sample LLD malfunction before movement 35-01-06	<p>E2010 stops the descending movement of the pipetter <u>on purpose</u> in order to prevent the probe from going too deep into the sample:</p> <p>(1) The pipetter probe end is wet or dirty badly. (2) Or the outer side of the sample container is wet badly with the dew drops. (3) Or the inner side of the sample container is wet <u>badly</u> with the sample. (4) The pipetter probe is damaged by the sample.</p> <p>Sub-code: Disk Type:Pos.No.1-30 and Test No. Rack Sampler Type: Rack ID, Pos.No.1-5 and Test No.</p>	<p>a. Wipe the pipetter probe end (Teflon tip). b. Or if the sample container is wet with the dew drops, wipe the dew drops.</p>

Alarm No.	Level	Alarm message	Alarm Description	Remedy
35_01_07	W	Sample LLD malfunction during movement 35-01-07	E2010 stops the descending movement of the pipetter on purpose in order to prevent the probe from going too deep into the sample because of following reasons. (1) The pipetter probe end is wet or dirty. (2) Or the outer side of the sample container is wet with the dew drops. (3) Or the inner side of the sample container is wet with the sample. Sub-code: Disk Type:Pos.No.1-30 and Test No. Rack Sampler Type: Rack ID, Pos.No.1-5 and Test No.	a. Wipe the pipetter probe end (Teflon tip). b. Or if the sample container is wet with the dew drops, wipe the dew drops. c. Or change the sample container.
35_03_01	W	Sample short (no LLD before z-max) 35-03-01	The pipetter does not detect a liquid level at the sample position due to insufficient sample or nothing in the sample container and then the pipetter touches the bottom of the sample container because the sample is short or there is no sample (The sample volume is shorter than the dead volume specification.). Sub-code: Disk Type:Pos.No.1-30 and Test No. Rack Sampler Type: Rack ID, Pos.No.1-5 and Test No.	a. Check sample volume. b. Check that tubes are properly placed on the sample disk or rack. c. If the sample volume is adequate and tubes are in place, call Technical Support.

Alarm No.	Level	Alarm message	Alarm Description	Remedy
35_03_02	W	Sample short (bottom-out after LLD) 35-03-02	The pipetter detect a liquid level at the sample position. But the pipetter touches the sample container bottom because the sample volume is too small. Sub-code: Disk Type:Pos.No.1-30 and Test No. Rack Sampler Type: Rack ID, Pos.No.1-5 and Test No.	a. Check sample volume. b. Check that tubes are properly placed on the sample disk. c. Retry in Hitachi Standard Cups with Reduced Mode. d. If the error recurs, call Technical Support
35_03_03	W	Sample short (bottom-out at aspiration) 35-03-03	The pipetter detect a liquid level at the sample position. But the pipetter touches the sample container bottom when it aspirates the sample because the sample volume is shorter than the dead volume specification. Sub-code: Disk Type:Pos.No.1-30 and Test No. Rack Sampler Type: Rack ID, Pos.No.1-5 and Test No.	
35_04_01	W	Sample short (before aspiration) 35-04-01	The pipetter could not completely detect a liquid level in the normal manner due to insufficient sample or nothing in sample container. Sub-code: Disk Type:Pos.No.1-30 and Test No. Rack Sampler Type: Rack ID, Pos.No.1-5 and Test No.	

Alarm No.	Level	Alarm message	Alarm Description	Remedy
35_04_02	W	Sample LLD noise (before aspiration) 35-04-02	E2010 recognizes this imperfect liquid level detection after the pipetter Z-movement stops because Static charges or other noises causes the imperfect sample liquid level detection. Sub-code: Disk Type:Pos.No.1-30 and Test No. Rack Sampler Type: Rack ID, Pos.No.1-5 and Test No.	a. Remove the static electricity charge. b. Change from the plastic tube to the glass tube. c. Remove the bubble. d. Add the sample.
35_04_03	W	Sample LLD noise (after aspiration) 35-04-03	E2010 recognizes this imperfect liquid level detection after the pipetter aspirates the sample because of following reasons; (1) Static charges, other noises causes the imperfect sample LLD. (2) Or the pipetter touches the wet on the wall of the sample container (3) Or the pipetter tip is close to the wall of the sample container then the sample climbed up to between tip and the inner side of the container. (4) Or the sample is short (The sample volume is shorter than the dead volume specification.). Sub-code: Disk Type:Pos.No.1-30 and Test No. Rack Sampler Type: Rack ID, Pos.No.1-5 and Test No.	

Temperatures (R.Disk, Incubator, Cell, PC/CC)

Alarm No.	Level	Alarm message	Alarm Description	Remedy
36_01_02	W	R.Disk temp.out of range. Ini.check 30min 36-01-02	The temperature of the R. disk exceeds the tolerance limit for 30 min or more. (-0.46*(outside temperature of R. disk) +29.0) 4.0 °C	<ul style="list-style-type: none"> a. Verify that the R. Disk cover is securely in place. b. Check that the fans at the back of the analyzer are operating normally. c. Check that the room temperature is between 18 °C and 32 °C. d. If the error recurs, call Technical Support.
36_02_02	W	Incub.temp. out of range.Ini.check 30 min. 36-02-02	The temperature of the incubator exceeds the tolerance limit for 30 min or more. (370±0.5 °C)	<ul style="list-style-type: none"> a. Check that the fans at the back of the analyzer are operating normally. b. Check that the room temperature is between 18 °C and 32 °C. c. If the error recurs, call Technical Support.
36_03_02	W	MC temp out of range. Ini.check 30 min. 36-03-02	The temperature of the cell exceeds the tolerance limit for 30 min or more. (-0.10*(outside temperature of detection unit)+30.0) ±0.5 °C	<ul style="list-style-type: none"> a. Verify temperature of ProCell/CleanCell on the analyzer. b. Check that the fans at the back of the analyzer are operating normally. c. Check that the room temperature is between 18 °C and 32 °C. d. If the error recurs, call Technical Support.
36_04_02	W	PC/CC temp.out of range. Ini.check 30 min.36-04-02	The temperature of PC/CC exceeds the tolerance limit for 30 min or more. (28.0±2.5 °C)	

Alarm No.	Level	Alarm message	Alarm Description	Remedy
36_05_01	W	PC/CC reag. bottle set 1 wasn't at 28°C 36-05-01	The temperature of system reagent position*1 is not in equilibrium.	a. Ensure that ProCell/CleanCell reagent was at 28 °C prior to operation. b. If reagent has been on the analyzer longer than 15 min., remove liquid from the bottle(s) so that the liquid level is approx. 1 inch (2.5 cm) from the top of the bottle. If you remove a bottle from positions 2 or 3 (where the photosensors are located), the analyzer considers that bottle set to be "new" and will not use the set for 15 minutes.
36_05_03	W	PC/CC reag. bottle set 2 wasn't at 28°C 36-05-03	The temperature of system reagent position*2 is not in equilibrium.	c. If the error recurs, call Technical Support.
36_05_05	Stop	PC/CC bottle sets 1 and 2 not at 28°C 36-05-05	The temperature of system reagent positions 1 and 2 are not in equilibrium.	

Assay Reagent

Alarm No.	Level	Alarm message	Alarm Description	Remedy
37_01_01	W	No LLD of assay reagent for test no. x 37-01-01	The pipetter does not detect liquid level for the assay reagent for Test ***. Subcode: test No.	<ul style="list-style-type: none"> a. Check reagent volume. b. If the reagent volume is adequate, access the VOLTAGE MONITOR screen from the UTILITY screen. If the S/R probe LLD voltage is > 2.00 V, then clean the S/R probe. c. If the alarm recurs immediately, call Technical Support.
37_01_02	W	No LLD of diluent for test no. x 37-01-02	The assay reagent is short for Test ***.	<ul style="list-style-type: none"> a. Check the number of remaining tests on the INVENTORY screen. Replace the appropriate reagent pack. b. Perform a Reagent Scan after replacement. If the error recurs, call Technical Support.
37_01_04	W	Film detected in assay reagent test no. x 37-01-04	Pipetter film was detected on pipetting of the assay reagent for Test ***. Subcode: test No.	<ul style="list-style-type: none"> a. Check for bubbles in the reagent pack. Eliminate any bubbles that may be present. b. If the alarm recurs immediately, call Technical Support.
37_01_05	W	Premature LLD hovering on assay rackpack 37-01-05	Hovering on the assay reagent bottle (Liquid level is misdetected due to static electricity or film.)	<ul style="list-style-type: none"> a. Check for moisture on the reagent pack lids. b. Access the VOLTAGE MONITOR screen from the UTILITY screen. If the S/R probe LLD voltage is > 2.00 V, then clean the S/R probe. c. If the voltage is still > 2.00 V, call Technical Support.
37_01_06	W	Premature LLD hovering on assay rackpack 37-01-06	Hovering on the assay reagent bottle [Environmental error: heavy] (The LLD function fails because of a significant increase in water conductivity or conduction of the nozzle.)	

Alarm No.	Level	Alarm message	Alarm Description	Remedy
37_01_07	W	Premature LLD hovering on assay rackpack 37-01-07	Hovering on the assay reagent bottle [Environmental error:light] (The LLD function fails because of an increase in water conductivity.)	<ol style="list-style-type: none"> Check for moisture on the reagent pack lids. Access the VOLTAGE MONITOR screen from the UTILITY screen. If the S/R probe LLD voltage is > 2.00 V, then clean the S/R probe. If the voltage is still > 2.00 V, call Technical Support.

Diluent

Alarm No.	Level	Alarm message	Alarm Description	Remedy
37_02_01	W	LL of diluent for testno.x not detected 37-02-01	The pipettor does not detect liquid level for the diluent for Test ***. Subcode: test No.	<ol style="list-style-type: none"> Check diluent volume. If the diluent volume is adequate, access the VOLTAGE MONITOR screen from the UTILITY screen. If the S/R probe LLD voltage is > 2.00 V, then clean the S/R probe. If the alarm recurs immediately, call Technical Support
37_02_02	W	Diluent vol. inadequate for test no. x 37-02-02	The diluent is short for Test ***. Subcode: test No.	<ol style="list-style-type: none"> Check for bubbles in the diluent reagent pack. Eliminate any bubbles that may be present. Check the number of mls remaining on the INVENTORY screen. Replace the diluent reagent pack. Perform a Reagent Scan after replacement. If the error recurs, call Technical Support.

Alarm No.	Level	Alarm message	Alarm Description	Remedy
37_02_04	W	Film detected in diluent for test no. x 37-02-04	Pipetter film was detected on pipetting of diluent. Subcode: test No.	a. Check for bubbles in the diluent reagent pack. Eliminate any bubbles that may be present. b. If the alarm recurs immediately, call Technical Support.
37_02_05	W	Premature LLD hovering on diluent test x 37-02-05	Hovering on the diluent bottle (Liquid level is misdetected due to static electricity or film.)	a. Check for moisture on the reagent pack lids. b. Access the VOLTAGE MONITOR screen from the UTILITY screen. If the S/R probe LLD voltage is > 2.00 V, then clean the S/R probe. c. If the voltage is still > 2.00 V, call Technical Support.
37_02_06	W	Premature LLD hovering on diluent test x 37-02-06	Hovering on the diluent bottle [Environmental error: heavy] (The LLD function fails because of a significant increase in water conductivity or conduction of the nozzle.)	
37_02_07	W	Premature LLD hovering on diluent test x 37-02-07	Hovering on the diluent bottle [Environmental error: light] (The LLD function fails because of an increase in water conductivity.)	

Pretreatment

Alarm No.	Level	Alarm message	Alarm Description	Remedy
37_03_01	W	LL of pretreatment testno. x not detected 37-03-01	The pipetter does not detect liquid level for the pretreatment for Test ***. Subcode: test No.	<ul style="list-style-type: none"> a. Check pretreatment volume. b. If the pretreatment volume is adequate, access the VOLTAGE MONITOR screen from the UTILITY screen. If the S/R probe LLD voltage is > 2.00 V, then clean the S/R probe. c. If the alarm recurs immediately, call Technical Support.
37_03_02	W	Pretreatment vol.inadequate for test x 37-03-02	The pretreatment is short for Test ***. Subcode: test No.	<ul style="list-style-type: none"> a. Check the number of tests remaining on the INVENTORY screen. Replace the pretreatment reagent pack. b. Perform a Reagent Scan after replacement. If the error recurs, call Technical Support.
37_03_04	W	Film detected in pretreat. for testno. x 37-03-04	Pipetter film was detected for pretreatment. Subcode: test No.	<ul style="list-style-type: none"> a. Check for bubbles in the pretreatment reagent pack. Eliminate any bubbles that may be present. b. If the alarm recurs immediately, call Technical Support.
37_03_05	W	Premature LLD hovering on pretreat.test x 37-03-05	Hovering on the pretreatment reagent bottle (Liquid level is misdetected due to static electricity or film.)	<ul style="list-style-type: none"> a. Check for moisture on the reagent pack lids. b. Access the VOLTAGE MONITOR screen from the UTILITY screen. If the S/R probe LLD voltage is > 2.00 V, then clean the S/R probe. c. If the voltage is still > 2.00 V, call Technical Support.

Alarm No.	Level	Alarm message	Alarm Description	Remedy
37_03_06	W	Premature LLD hovering on pretreat.test x 37-03-06	Hovering on the pretreatment reagent bottle [Environmental error: heavy] (The LLD function fails because of an increase in water conductivity.)	a. Check for moisture on the reagent pack lids. b. Access the VOLTAGE MONITOR screen from the UTILITY screen. If the S/R probe LLD voltage is > 2.00 V, then clean the S/R probe. c. If the voltage is still > 2.00 V, call Technical Support.
37_03_07	W	Premature LLD hovering on pretreat.test x 37-03-07	Hovering on the pretreatment reagent bottle [Environmental error: light] (The LLD function fails because of a significant increase in water conductivity or conduction of the nozzle.)	

BlankSet

Alarm No.	Level	Alarm message	Alarm Description	Remedy
37_04_01	W	Liq. Level of BlankCell not detected 37-04-01	The pipettor does not detect liquid level for the BlankSet. Subcode: test No.	a. Check BlankCell volume. b. If the BlankCell volume is adequate, access the VOLTAGE MONITOR screen from the UTILITY screen. If the S/R probe LLD voltage is > 2.00 V, then clean the S/R probe. c. If the alarm recurs immediately, call Technical Support.

Alarm No.	Level	Alarm message	Alarm Description	Remedy
37_04_02	W	BlankCell reagent was inadequate 37-04-02	The BlankSet is short for Test ***. Subcode: test No	<ul style="list-style-type: none"> a. Check the number of tests remaining on the INVENTORY screen. Replace the BlankCell reagent pack. b. Perform a Reagent Scan after replacement. If the error recurs, call Technical Support.
37_04_04	W	Film detected in BlankCell reagent 37-04-04	Pipettor Film was detected on pipetting of Blank Set.	<ul style="list-style-type: none"> a. Check for bubbles in the BlankCell reagent pack. Eliminate any bubbles that may be present. b. If the alarm recurs immediately, call Technical Support.
37_04_05	W	Premature LLD hovering over BlankCell 37-04-05	Hovering on the BlankSet bottle (Liquid level is misdetected due to static electricity or film.)	<ul style="list-style-type: none"> a. Check for moisture on the reagent pack lids. b. Access the VOLTAGE MONITOR screen from the UTILITY screen. If the S/R probe LLD voltage is > 2.00 V, then clean the S/R probe. c. If the voltage is still > 2.00 V, call Technical Support.
37_04_06	W	Premature LLD hovering over BlankCell 37-04-06	Hovering on the BlankSet bottle [Environmental error: heavy] (The LLD function fails because of a significant increase in water conductivity or conduction of the nozzle.)	
37_04_07	W	Premature LLD hovering over BlankCell 37-04-07	Hovering on the BlankSet bottle [Environmental error: light] (The LLD function fails because of an increase in water conductivity.)	

ProCell/CleanCell

Alarm No.	Level	Alarm message	Alarm Description	Remedy
37_05_01	W	No sipper-LLD in PC/CC set 1 or 2 37-05-01	The sipper does not detect liquid level for the PC/CC. (Only 1 set)	a. Ensure that there is a ProCell/CleanCell bottle set in the system reagent compartment. b. If bottles are present, call Technical Support.
37_05_02	Stop	No sipper-LLD in PC/CC sets 1 and 2 37-05-02	The sipper does not detect liquid level for the PC/CC. (Neither set 1 nor set 2)	a. Ensure that there are ProCell/CleanCell bottle sets in the system reagent compartment. b. If bottles are present, call Technical Support.
37_05_03	Stop	ProCell/CleanCell volumes are inadequate 37-05-03	PC/CC is short	a. Check the number of tests remaining on the INVENTORY screen. Replace the appropriate reagent pack. b. If the error recurs after replacement, call Technical Support.
37_06_01	W	PC/CC film detected (Pos 1) 37-06-01	Film is detected at PC/CC Pos. 1 during aspiration.	a. Check for bubbles in the ProCell and CleanCell bottles in Set 1 (positions 1 and 2). Eliminate any bubbles that may be present. b. If the error recurs, call Technical Support.
37_06_02	Stop	PC/CC film detected (Pos 1) 37-06-02	Film is detected at PC/CC Pos. 1 during level check	
37_06_03	W	PC/CC film detected (Pos 2) 37-06-03	Film is detected at PC/CC Pos. 2 during aspiration.	a. Check for bubbles in the ProCell and CleanCell bottles in Set 2 (positions 3 and 4). Eliminate any bubbles that may be present. b. If the error recurs, call Technical Support.
37_06_04	Stop	PC/CC film detected (Pos 2) 37-06-04	Film is detected at PC/CC Pos. 2 during level check	

Alarm No.	Level	Alarm message	Alarm Description	Remedy
37_06_05	Stop	PC/CC film detected 37-06-05	PC/CC not available due to film detection during aspiration.	a. Check for bubbles in the ProCell and CleanCell bottles in Sets 1 and 2. Eliminate any bubbles that may be present. b. If the error recurs, call Technical Support.
37_07_01	W	System reagent bottle change over 37-07-01	System reagent bottles change over to the others during operation cycle. Sub-code: Seq.No. of the corresponding sample	Only inform of changing over. No action is necessary.

Bar Code

Alarm No.	Level	Alarm message	Alarm Description	Remedy
38_01_01	W	Reagent BC scan pos. x unsuccessful 38-01-01	Incorrect RackPack bard code reading. (Only during RackPack bar code reader check) Sub-code: Regent .Pos No.1-18	a. Verify the label is not smeared or damaged. b. Verify the R. Disk BCR window is clean. c. If the error recurs, call Technical Support.
38_01_02	W	Sample BC scan pos. x unsuccessful 38-01-02	Incorrect sample bar code reading.(Only during sample bar code reader check) Sub-code: Disk type:Sample.Pos No.1-30 Rack Sampler type: Sample pos No.:1-5	a. Verify the label is not smeared or damaged. b. If the error recurs, call Technical Support.

Alarm No.	Level	Alarm message	Alarm Description	Remedy
38_01_03	W	Bar code card scan was unsuccessful 38-01-03	Incorrect bar code card reading.	<ul style="list-style-type: none"> a. Verify the bar code card is not reversed. b. Verify the label is not smeared or damaged. c. If the error recurs, call Technical Support.
38_01_04	W	Communication error between BCR/analyzer 38-01-04	Communication error with the bar code reader (parity, framing, overrun).	Call Technical Support.
38_02_01	W	BCR failed to read ID on B-Line 38-02-01	B line mechanism: Rack ID reading error.	<ul style="list-style-type: none"> a. Verify the rack label is not smeared or damaged. b. For manually-entered rack IDs, verify you entered the correct number of digits (4 or 5). This number is determined during analyzer installation. c. If the error recurs, call Technical Support.
38_02_03	W	Comm. err. between BCR B-Line/analyzer 38-02-03	B line mechanism: Error in the communication with the barcode reader.	Call Technical Support.

Cups and Tips

Alarm No.	Level	Alarm message	Alarm Description	Remedy
39_01_01	W	Tip tray is empty, failure to pickup a tip 39-01-01	Either there are no tips in the tip container or it was determined to be empty due to pickup failure (when one of the containers is empty).	a. Replace the tip tray(s). Perform a Reagent Scan. b. If the error recurs, call Technical Support.
39_01_02	P.Stop/ S.Stop	All tip trays empty, didn't pickup a tip 39-01-02	Either there are no tips in the tip container or it was determined to be empty due to pickup failure (other than during preparation when all 3 are empty: P. STOP, Operation. when all 3 are empty: S. STOP).	
39_02_01	W	Cup tray or tray empty, didn't pickup cup 39-02-01	Either there are no tips in the vessel container or it was determined to be empty due to pickup failure (when one container is empty).	a. Replace the cup tray(s). Perform a Reagent Scan. b. If the error recurs, call Technical Support.
39_02_02	P.Stop	All cup trays empty, didn't pickup cup 39-02-02	Either there are no tips in the vessel container or it was determined to be empty due to pickup failure (when all three are empty).	

BlankCell

Alarm No.	Level	Alarm message	Alarm Description	Remedy
40_01_01	W	BlankCell procedure was unsuccessful. 40-01-01	Failed in measurement of the BlankSet.	The BlankCell Procedure is reserved for service. Call Technical Support for assistance.
40_01_02	W	Expired BlankCell data or no valid data 40-01-02	BlankSet is invalid because the reproducibility period has expired or there is no valid BlankSet data.	<p>The BlankCell Procedure is reserved for service.</p> <ol style="list-style-type: none"> If BlankCell is on the R. disk, remove the reagent pack and perform a reagent scan. If BlankCell remains on the INVENTORY screen, call Technical Support.

Floppy Disk Drive

Alarm No.	Level	Alarm message	Alarm Description	Remedy
41_01_01	W	Floppy disk was write protected 41-01-01	F/D is write-protected.	<ul style="list-style-type: none"> a. Check for a floppy disk in the disk drive. b. Check if the floppy disk is write-protected. If it is, then remove the write-protection and try again. c. If the floppy disk is not write-protected and the alarm recurs, call Technical Support.
41_01_03	W	Floppy disk write error 41-01-03	<ul style="list-style-type: none"> 1. There is no appropriate file in the F/D (during auto backup). 2. Available space on the F/D is less than the file size (during F/D Utility backup). 3. F/D is not inserted. 4. F/D is damaged. 	<ul style="list-style-type: none"> a. Check for a floppy disk in the disk drive. b. Verify the floppy disk is not damaged. c. Access the MAINTENANCE screen and perform an FD write with a new, formatted floppy disk. d. If the error recurs, call Technical Support.
41_01_04	W	Floppy disk read error. 41-01-04	<ul style="list-style-type: none"> 1. There is no appropriate file on the F/D. 2. F/D is not inserted. 3. F/D is damaged. 	
41_01_05	W	FD has been accessed >100,000 times 41-01-05	Number of access times to F/D has exceeded 100,000	Access the MAINTENANCE screen and perform an FD write with a new, formatted floppy disk.

Alarm No.	Level	Alarm message	Alarm Description	Remedy
41_01_06	Stop	Data disk error 41-01-06	<ol style="list-style-type: none"> 1. There is no appropriate file on the F/D (**00.dat). 2. F/D is not inserted. 3. F/D is damaged. 4. APC was performed during access to the F/D. 	<ol style="list-style-type: none"> a. Check for a floppy disk in the disk drive. b. Verify the floppy disk is not damaged. c. Perform a system reset from the MAINTENANCE screen. d. If the error recurs, call Technical Support.
41_01_07	Stop	Data disk error 41-01-07	<ol style="list-style-type: none"> 1. There is no appropriate file on the F/D. 2. F/D is damaged. 	
41_01_08	Stop	Data disk error 41-01-08	<ol style="list-style-type: none"> 1. There is no appropriate file on the F/D (**00.dat). 2. F/D is not inserted. 3. F/D is damaged. 	
41_01_09	W	Execute FDD cleaning and exchange FD 41-01-09	F/D write is fail because F/D is damaged.	
41_01_10	W	FD write err. (Initialization) 41-01-10	<ol style="list-style-type: none"> 1. There is no appropriate file in the F/D (during auto backup). 2. F/D is not inserted. 3. F/D is damaged. 	
42_02_01	W	Printer error 42-02-01	Printer has trouble (not ready, no paper, etc.).	
				<ol style="list-style-type: none"> a. Verify the printer cable is firmly connected. b. Verify the power is on. c. Verify the printer is on-line. d. Replenish printer paper. e. If the error recurs, call Technical Support.

Communication-Control Unit

Alarm No.	Level	Alarm message	Alarm Description	Remedy
43_01_01	W	Communication error touchscreen/analyzer 43-01-01	Message was sent again during transmission of the message.	a. Verify the touchscreen cable is firmly connected. b. If the error recurs, call Technical Support.

Interface Communication

Alarm No.	Level	Alarm message	Alarm Description	Remedy
44_01_01	W	A retry occurred at message transmission 44-01-01	Message was aborted in the middle of a transmission.	a. Verify the host system cable is firmly connected.
44_01_02	W	Communication abort at mess. transmission 44-01-02	Reception of the message was aborted.	b. Verify communication settings in the INTERFACE SETUP screen.
44_01_03	W	Communication abort at receiving message 44-01-03	Re-sending of the message was aborted.	c. If the error recurs, call Technical Support.
44_01_04	W	Message retransmission was unsuccessful 44-01-04	Re-sending of message failed (low level).	
44_01_05	W	Message retransmission was unsuccessful 44-01-05	Re-sending of message failed (low level).	
44_01_06	W	Timeout occurred at message transmission 44-01-06	Time out (low level)	

Alarm No.	Level	Alarm message	Alarm Description	Remedy
44_01_07	W	Timeout occurred while receiving message 44-01-07	Time out (low level)	a. Verify the host system cable is firmly connected. b. Verify communication settings in the INTERFACE SETUP screen. c. If the error recurs, call Technical Support.
44_01_08	W	Communication format was incorrect. 44-01-08	1. There is a valid record but no termination record. 2. There is no valid record. 3. The first record is not a header record. 4. There is an undefined record. 5. There is data other than that defined.	
44_01_09	W	Update of a database was not allowed 44-01-09	Unable to renew data to the DB	
44_01_10	W	A hardware error occurred 44-01-10	Hardware error.	
44_01_11	W	A software error occurred 44-01-11	Application error.	
44_01_12	W	Upload is defined but host com. is OFF 44-01-12	No host was detected.	a. Verify the host system is on. b. Verify the host system cable is firmly connected. c. Verify communication settings in the INTERFACE SETUP screen. d. Verify document settings in the DOCUMENTATION SETUP screen. e. If the error recurs, call Technical Support.

Inventory

Alarm No.	Level	Alarm message	Alarm Description	Remedy
45_01_01	Stop	Assay reagent inadequate or not on board 45-01-01	Unable to measure the amount of the inventory (REAGENT).	a. Check the number of tests remaining on the INVENTORY screen. Replace the appropriate reagent pack. b. Perform a Reagent Scan after replacement. If the error recurs, call Technical Support.
45_01_02	Stop	No or inadequate RackPacks on R. Disk 45-01-02	No assay reagent rackpack is available	
45_04_01	Stop	BlankCell R1 was inadequate 45-04-01	Unable to measure the amount of the inventory (BLANKSET1).	a. Check the R1 or R2 position of the BlankCell reagent pack. Replace the BlankCell reagent pack, if necessary. b. Perform a Reagent Scan after replacement. If the error recurs, call Technical Support.
45_05_01	Stop	BlankCell R2 was inadequate 45-05-01	Unable to measure the amount of the inventory (BLANKSET2).	
45_06_01	Stop	Tips were inadequate for analyzer 45-06-01	Unable to measure the amount of the inventory (TIP).	a. Replace the empty tip tray(s), if necessary. Perform a Reagent Scan. b. If the error recurs, call Technical Support.
45_07_01	Stop	Cups were inadequate for analyzer 45-07-01	Unable to measure the amount of the inventory (VESSEL).	
45_08_01	Stop	Volume of PC/CC was inadequate 45-08-01	Unable to measure the amount of the inventory (PCCC).	a. Check the percentage remaining on the INVENTORY screen. Replace the reagent bottle, if necessary. b. If the error recurs after replacement, call Technical Support.
46_01_01	P.Stop	Incubator was full 46-01-01	Incubator is full.	a. Perform a system reset from the MAINTENANCE screen. b. Start operation. c. If any cup is left in the incubator after initialization, call Technical Support.

Alarm No.	Level	Alarm message	Alarm Description	Remedy
47_01_01	Stop	More than 15 assays on analyzer: 47-01-01	RP bar code information registration for assay + pretreatment has exceeded 15.	<ol style="list-style-type: none"> Check the reagent packs on the R. Disk. Remove the appropriate number of assay reagent packs. Perform a Reagent Scan after removal. If the error recurs, call Technical Support.
47_01_02	Stop	More than eight diluents on analyzer 47-01-02	RP bar code information registration for the diluent has exceeded 8.	<ol style="list-style-type: none"> Check the reagent packs on the R. Disk. Remove the appropriate number of diluent reagent packs. Perform a Reagent Scan after removal. If the error recurs, call Technical Support.
47_01_03	Stop	More than one BlankCell on analyzer 47-01-03	RP bar code information registration for the BlankSet is more than 1.	<ol style="list-style-type: none"> Check the reagent packs on the R. Disk. Remove the appropriate number of BlankCell reagent packs. Perform a Reagent Scan after removal. If the error recurs, call Technical Support.

System Volume Range

Alarm No.	Level	Alarm message	Alarm Description	Remedy
48_01_01	W	Sipper pipettor aspiration problem 48-01-01	System volume value is outside the range.	Call Technical Support.

Clot Detection

Alarm No.	Level	Alarm message	Alarm Description	Remedy
49_01_01	W	Sample volume insufficient or clot pip. 49-01-01	<p>The pipettor cannot aspirate the sample because of the following reasons:</p> <p>(1) Clot or fibrin prevents the pipettor from aspirating.</p> <p>(2) Or the pipettor touches the bottom of the sample container due to the short sample (The sample volume is shorter than the dead volume specification.).</p> <p>Sub-code; Disk type: Sample Pos No.1-30 and Test No. Rack sampler type: Rack ID, Sample Pos.No. 1-5 and Test No.</p>	<p>a. Check the sample volume.</p> <p>b. Check the sample for clots.</p> <p>c. Repeat the sample.</p> <p>d. If the error recurs, call Technical Support.</p>

Sample ID

Alarm No.	Level	Alarm message	Alarm Description	Remedy
50_01_01	W	Sa. BC not scanned just prior to sampling 50-01-01	PSID: Unable to read before sampling but able to read during SSCAN. Sub-code; Disk type: Sample Pos No.1-30 Rack sampler type: Rack ID and Sample Pos.No. 1-5.	a. Verify that sample tubes are not removed until the STATUS screen reads "Remov." b. Verify that the sample bar code label is not damaged. c. Rerun the sample.
50_01_02	W	Sa. BC was scanned just prior to sampling 50-01-02	PSID: Able to read before sampling but unable to read during SSCAN. Sub-code; Disk type: Sample Pos No.1-30 Rack sampler type: Rack ID and Sample Pos.No. 1-5.	
50_01_03	W	Diff. BC info before/at lable scan 50-01-03	PSID: ID read before sampling does not match ID read during SSCAN. Sub-code; Disk type: Sample Pos No.1-30 Rack sampler type: Rack ID and Sample Pos.No. 1-5.	
50_02_01	W	SampleID registered,BC-scan unsuccessful 50-02-01	The Sample position can not read Sample ID but that position have programmed already sample ID. Sub-code: Seq No.1-9999	a. Verify there is a sample in the position. b. Verify that the sample bar code label is not damaged. c. If the error recurs, call Technical Support.

Alarm No.	Level	Alarm message	Alarm Description	Remedy
50_02_02	W	Stored sample detached from pos. 50-02-02	Stored sample detached from pos. Sub-code: Disk type: Sample Pos.No.1-30 and Test No. Rack Sampler type: Rack ID, Sample Pos.No.1-5 and Test No.	Check the sample ID No. on the sample position. Retry Sample Scan and order test
50_02_03	W	No programming/ID for sample pos. 50-02-03	No programming/ID for sample pos. Sub-code: Disk type: Sample Pos.No.1-30 and Test No. Rack Sampler type: Rack ID, Sample Pos.No.1-5 and Test No.	
50_02_04	W	Sample could not be processed 50-02-04	Sample could not be processed: no demands for this sample in the system. Sub-code: Disk type: Sample Pos.No.1-30 and Test No. Rack Sampler type: Rack ID, Sample Pos.No.1-5 and Test No.	Check the test order and the reagents (Assay/Pretreatment/Diluent) on the instrument

Gripper Adjustment

Alarm No.	Level	Alarm message	Alarm Description	Remedy
51_01_01	W	Gripper failure during autom. adjustment 51-01-01	There was an item that was not adjusted during automatic adjustment.	Call Technical Support.
51_01_02	W	Gripper failure during autom. adjustment 51-01-02	There was an item that was not fully adjusted due to it being up to the limit during automatic adjustments.	

AC Power

Alarm No.	Level	Alarm message	Alarm Description	Remedy
52_01_01	W	AC power failure 52-01-01	Power failure.	a. Perform a system reset from the MAINTENANCE screen. b. If the error recurs, call Technical Support.

CPU Error

Alarm No.	Level	Alarm message	Alarm Description	Remedy
53_01_01	W	Analyzer previously had a CPU lock up 53-01-01	CPU error 1 due to power outage.	No action necessary. For information only.

Calibration

Alarm No.	Level	Alarm message	Alarm Description	Remedy
54_01_01	W	No calibrator card was read 54-01-01	No Calibration Bar-code card was read. Sub-code: Test No.	<ul style="list-style-type: none"> a. Perform a bar code card scan of the appropriate calibrator bar code card. b. If the error recurs, call Technical Support.
54_01_02	W	CalSet was expired 54-01-02	The calibrator was expired. Sub-code: Test No.	<ul style="list-style-type: none"> a. Verify the expiration date of the appropriate CalSet. b. Replace the CalSet if necessary and initiate calibration again. c. If the expiration date on the CalSet is still valid, call Technical Support.
54_01_03	W	No rackpack that can be used for calib. 54-01-03	There was no reagent RackPack (Assay/Pre-treatment) on the instrument that can be used for calibration. Sub-code: Test No.	<ul style="list-style-type: none"> a. Verify that the appropriate reagent packs are on the reagent disk, especially pretreatment reagent. b. If all the appropriate reagent packs appear to be on the reagent disk and the alarm occurs again, call Technical Support.
54_01_04	W	CalSet was not complete; no calibration 54-01-04	Calibration could not be executed because the calibrator set were not complete. Sub-code: Test No.	<ul style="list-style-type: none"> a. Verify that there are complete (one Cal 1 and one Cal 2) and matched (both vials are of the same lot and for the same assay) CalSets on the sample disk or in racks. b. If all CalSets are complete and matching and the alarm occurs again, call Technical Support.

Samples

Alarm No.	Level	Alarm message	Alarm Description	Remedy
55_01_01	W	No tests ordered for STAT sample at pos.x 55-01-01	No test were ordered for a STAT sample at this sample position. Sub-code: Disk type: Sample Pos. No.1-30 Rack sampler type: Rack ID and Sample Pos.No.1-5	Verify the test selection for the STAT sample in the ORDERS screen or print a Status report.
56_01_01	W	All samples were pipetted 56-01-01	All samples were pipetted.	For information only. No action necessary.

Serial No.

Alarm No.	Level	Alarm message	Alarm Description	Remedy
57_01_01	W	SN on data disk is different to analyzer 57-01-01	The serial No. read from the Data FD is different from serial No. of the instrument.	a. Verify you have the correct data disk in the analyzer. You cannot interchange data disks between analyzers. b. If you are using the correct data disk, call Technical Support.

Validity

Alarm No.	Level	Alarm message	Alarm Description	Remedy
58_01_01	W	Improper reagent pack for analyzer 58-01-01	Improper RackPack was entered in the instrument. Sub-code: Reagent pos.No.1-18	This reagent pack cannot be used on the analyzer, call Technical Support.
58_01_02	W	Improp. cal./cont. BC card for analyzer 58-01-02	Improper Barcode card was entered in the instrument.	This CalSet or control cannot be used on the analyzer, call Technical Support.

Database

Alarm No.	Level	Alarm message	Alarm Description	Remedy
59_01_01	W	> 15 control lot combinations defined 59-01-01	Control database becomes full	Delete oldest control data
59_01_02	W	Maximum Sample Data 59-01-02	You can order no more samples because the sample database becomes full	Carry out the sample data documentation

Maintenance

Alarm No.	Level	Alarm message	Alarm Description	Remedy
60_01_01	W	LFC is recommended 60-01-01	more than two weeks have passed since last LFC	Carry out LFC

Rack Sampler/Rack Sampler connected to CLAS 1 System



- W: Warning
- L: Line alarm
 - An alarm occurred on a line.
- AL: A line stop
 - An alarm occurred on the A line.
- IL: I line stop
 - An alarm occurred on the I line, turntable C and the turn belt.
- R: Rack supplying stop
- S: Stop
- P: P. Stop (partial stop)
- E.S E. Stop (emergency stop)

A-Line

Alarm No.	Level	Alarm message	Alarm Description	Remedy
61_01_01	S	A-Line pusher didn't move from home pos. 61-01-01	A-Line mechanism: Does not move from the home position (during reset).	a. Perform an L and A Reset All from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
61_01_02	S	A-Line pusher didn't stop at home pos. 61-01-02	A-Line mechanism: Does not stop at the home position (during reset).	
61_01_04	AL/S	A-Line pusher bar didn't reach home pos. 61-01-04	A-Line mechanism: Does not stop at the home position.	a. When the analyzer returns to Stand-by, perform an L and A Reset All from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
61_01_05	AL/S	A-Line pusher bar didn't stop at home pos. 61-01-05	A-Line mechanism: Does not stop at the correct home detected.	
61_01_06	AL/S	A-Line pusher didn't stop at rack detect. 61-01-06	A-Line mechanism: Does not stop at the rack detected, and does not stop at the rack feed end position.	
61_01_07	AL/S	A-Line pusher bar no stop at rack detect. 61-01-07	A-Line mechanism: Does not stop at the rack detected, also does not stop at the correct rack feed end position detected.	
61_01_08	AL/S	A-Line pusher didn't stop at home pos. CLAS 61-01-08	A-Line mechanism: Does not stop at the home position. (for sampler connected to CLAS 1 system)	
61_01_09	AL/S	A-Line pusher didn't stop at home pos. CLAS 61-01-09	A-Line mechanism: Does not stop at the correct home detected. (for sampler connected to CLAS 1 system)	
61_02_01	R/S	All racks on A-Line were loaded 61-02-01	A-Line mechanism: Completed rack feed for all the racks.	For information only. No action necessary.
61_02_02	W	A tray was missing on A-Line 61-02-02	A-Line mechanism: Rack tray is missing.	a. Place a tray on the A-Line. b. If a tray is on the A-Line, call Technical Support.

B-Line

Alarm No.	Level	Alarm message	Alarm Description	Remedy
62_01_01	S	B-Line pusher didn't stop at home pos. 62-01-01	B-Line mechanism: Does not stop at the home position (during reset).	a. Perform an L and A Reset All from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
62_01_03	S	B-Line pusher didn't stop at STAT rack pos. 62-01-03	B-Line mechanism: Does not stop at the STAT rack position (during reset).	
62_01_04	L/S	B-Line pusher didn't stop at home pos. 62-01-04	B-Line mechanism: Does not stop at the home position.	a. When the analyzer returns to Stand-by, perform an L and A Reset All from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
62_01_06	L/S	B-Line pusher bar didn't reach STAT pos 62-01-06	B-Line mechanism: Does not stop at the STAT rack position.	
62_01_07	L/S	A rack didn't stop BC read pos. B-Line 62-01-07	B-Line mechanism: Rack does not stop at BC reading position.	
62_01_08	L/S	A rack didn't stop at Samp. pos. on B-Line 62-01-08	B-Line mechanism: Rack does not stop at the pipetting position.	
62_01_09	L/S	B-Line pusher bar didn't stop at home pos. 62-01-09	B-Line mechanism: Does not stop at the correct home detected.	
62_01_11	L/S	B-Line pusher bar didn't stop at STAT pos 62-01-11	B-Line mechanism: Does not stop at the proper STAT rack position detected.	
62_01_12	L/S	Rack didn't stop at BC read. pos. on B-Line 62-01-12	B-Line mechanism: Rack does not stop at the proper BC read detected.	
62_01_13	L/S	Rack didn't stop at Samp. pos. on B-Line 62-01-13	B-Line mechanism: Rack does not stop at the proper pipetting position detected.	
62_01_14	S	Rack didn't stop at R. receipt pos. CLAS 62-01-14	B-Line mechanism: Does not stop at the rack receipt position (during reset). (for sampler connected to CLAS 1 system)	

Alarm No.	Level	Alarm message	Alarm Description	Remedy
62_01_15	L/S	Rack didn't stop at R. receipt pos. CLAS 62-01-15	B-Line mechanism: Does not stop at the rack receipt position. (for sampler connected to CLAS 1 system)	a. When the analyzer returns to Stand-by, perform an L and A Reset All from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
62_01_16	L/S	Rack didn't stop at R. receipt pos. CLAS 62-01-16	B-Line mechanism: Rack does not stop at the proper rack receipt position detected. (for sampler connected to CLAS 1 system)	
62_01_17	L/S	Rack fed cannot be transf. inside CLAS 62-01-17	B-Line mechanism: Rack fed from the rotating mechanism C to the rack receipt position (PI218) cannot be transferred inside. (for sampler connected to CLAS 1 system)	
62_02_03	W	No rack detect on rack receipt of B-Line 62-02-03	B-Line mechanism: No rack on the rack receipt position from the A-Line to the B-Line.	a. Verify there is a rack loaded at the receipt position on the B-Line. b. If the error recurs, call Technical Support.
62_02_04	W	C-Line and buffer are full 62-02-04	B-Line mechanism: Rack cannot be sent to C-Line (rack buffer is also full).	a. Remove the full tray from the C-Line and replace it with an empty tray.
62_02_05	S	C-Line and buffer are full (at reset) 62-02-05	B-Line mechanism: Rack does not stop at the pipetting position (during reset).	b. If the C-Line and buffer are not full, call Technical Support.
62_02_06	L/S	No rack is fed from rotat. mechanism CLAS 62-02-06	B-Line mechanism: No rack is fed from the rotating mechanism. (For sampler connected to CLAS 1 system)	a. Verify there is a rack loaded. b. If the error recurs, call Technical Support.

C-Line

Alarm No.	Level	Alarm message	Alarm Description	Remedy
63_01_01	S	C-Line pusher didn't stop at home pos. 63-01-01	C-Line mechanism: Does not stop at the home position (during reset).	a. Perform an L and A Reset All from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
63_01_02	S	C-Line pusher didn't stop at rack rec.pos. 63-01-02	C-Line mechanism: Does not stop at the rack receipt end position (during reset).	
63_01_03	L/S	C-Line pusher bar didn't stop at home pos 63-01-03	C-Line mechanism: Does not stop at the home position.	a. When the analyzer returns to Stand-by, perform an L and A Reset All from the MAINTENANCE screen. b. If the error recurs, call Technical Support.
63_01_04	L/S	C-Line pusher didn't stop at rack rec.pos. 63-01-04	C-Line mechanism: Does not stop at the rack receipt end position.	
63_01_05	L/S	C-Line pusher didn't stop at home posit. 63-01-05	C-Line mechanism: Does not stop at the proper home position detected.	
63_01_06	L/S	C-Line pusher didn't stop at rack rec.pos. 63-01-06	C-Line mechanism: Does not stop at the detected rack receipt end position.	
63_01_07	S	C-Line pusher didn't send rack to buffer 63-01-07	C-Line mechanism: Unable to send rack to the buffer position (during reset).	
63_01_08	W	C-Line pusher didn't send rack to buffer 63-01-08	C-Line mechanism: Unable to send a rack to the buffer position.	a. Place a tray on the C-Line. b. If a tray was in place on the C-Line, call Technical Support.
63_02_01	W	A tray was missing on C-Line 63-02-01	C-Line mechanism: No rack recovery tray.	
63_02_02	W	C-Line tray was full of racks 63-02-02	C-Line mechanism: Rack recovery tray is full.	a. Remove the full tray from the C-Line and replace it with an empty tray. b. If the tray is not full, call Technical Support.

Rack Detection

Alarm No.	Level	Alarm message	Alarm Description	Remedy
71_01_01	W	There was no rack in STAT rack pos. 71-01-01	No STAT rack in the STAT rack position.	a. Place a rack in the STAT position. b. If there is a rack in the STAT position, call Technical Support.
71_01_02	IL/S	Improper timing when set Rack at I-Line 71-01-02	Rack is has been set at the I-Line buffer position with improper timing. (For sampler connected to CLAS 1 system)	Remove the rack from the I-Line.
71_01_03	L/S	Improper position when set Rack at B-Line 71-01-03	Rack has been set at an improper position on the B-Line.	Remove the rack from the B-Line.

Cup Detection

Alarm No.	Level	Alarm message	Alarm Description	Remedy
72_01_01	W	No samples detected in rack on B-Line 72-01-01	B-Line mechanism: There are no cups on the rack.	a. Verify the presence of samples (cups or primary tubes) on the rack in question. b. If cups or tubes are loaded on the rack, call Technical Support.

Others

Alarm No.	Level	Alarm message	Alarm Description	Remedy
73_01_02	E.S	Low DC+24V signal on DO4 circuit board 73-01-02	Low DC24V or blown fuse on the DO4 board or DO5 board.	<p>There is potentially an electronic problem.</p> <ol style="list-style-type: none"> When the analyzer returns to Stand-by, perform an L and A Reset All from the MAINTENANCE screen. Power the analyzer OFF at the circuit breaker, then ON. Before performing this step, refer to the Backup Data Disk heading on p. 3-7. If the error recurs, call Technical Support.
73_01_03	E.S	A clock err. in serial communication 73-01-03	Serial communication CLK error.	<ol style="list-style-type: none"> Verify the host system cable is firmly connected. Verify communication settings in the INTERFACE SETUP screen. Power the analyzer OFF at the circuit breaker, then ON. Before performing this step, refer to the Backup Data Disk heading on p. 3-7. If the error recurs, call Technical Support.

Alarm No.	Level	Alarm message	Alarm Description	Remedy
73_01_04	E.S	A blown fuse on PSCNT circuit board 73-01-04	Blown fuse on the PSCNT board.	<p>There is potentially an electronic problem.</p> <p>a. Power the analyzer OFF at the circuit breaker, then ON. Before performing this step, refer to the Backup Data Disk heading on p. 3-7.</p> <p>b. If the error recurs, call Technical Support.</p>
73_01_05	E.S	A blown fuse on DO4 or DO5 circuit board 73-01-05	Blown fuse on the DO4 board or DO5 board.	
73_01_06	E.S	An abnormal DC power supply 73-01-06	Abnormal DC power input.	
73_01_07	E.S	A blown fuse on RSCNT circuit board 73-01-07	<ol style="list-style-type: none"> 1. The sampler unit, loader unit or unloader unit was turned off while the instrument was turned on. 2. Alternatively, the sampler unit, loader unit or unloader unit was not turned on although the instrument was already turned on. 3. Blown fuse on the RS CONTA Board. 	
73_01_08	E.S	A power failure on rack sampler 73-01-08	Abnormal DC 5V	Call Technical Support.
73_01_09	E.S	DIST-CR fuse 73-01-09	Blown fuse on the DIST-CR board. (Sampler connected to CLAS 1 system)	
74_01_01	S.	BC Reader auto.adjust. failed on B line 74-01-01	B-Line mechanism: Automatic adjustment for rack B/C reading position failed	Call Technical Support.

4. Maintenance

4.1 Maintenance Procedure Overview

The following procedures are written for trained operators with a working knowledge of all instrument mechanical functions, software displays and software functions. The instrument must be provided with proper care and maintenance to ensure consistent and accurate functioning.

How to Use this Chapter

All maintenance procedures are listed in descending frequency. Each maintenance procedure is divided into two parts: the Introduction and the Procedure.

The Introduction provides important information about the procedure, which includes:

- recommended frequency
- materials required
- time required
- precautions.

The recommended frequency is based on using the analyzer 8 hours per day, 5 days per week. You may adjust your maintenance frequency based on your laboratory's actual usage.

The materials required provides you with a list of all materials needed to perform each procedure.

The time required includes both operator time and analyzer time, when appropriate.

Precautions are included for your protection.

The Procedure gives step-by-step directions for performing the required maintenance function. This part frequently is divided into smaller procedure blocks to help you organize your approach to maintenance.

Replacement Parts

A replacement part may be needed for a specific maintenance procedure. That part's description and catalog number are included in the Materials Required table of each procedures' Introduction. Please use the catalog number when ordering replacement parts. Remember, you are responsible for maintaining an adequate spare parts inventory.

For most efficient use of time, gather all required materials before starting the maintenance procedure.

Maintenance Schedule

Detailed descriptions of the maintenance procedures listed below are found later in this chapter.

Daily

Clean S/R probe

Finalization maintenance

Weekly

Clean incubator and aspiration station

Clean sipper probe

Every 2 Weeks

Clean rinse stations for S/R probe, mixer and sipper probe
Perform Liquid Flow Cleaning

Monthly

Clean floppy disk drive

As Needed

Clean distilled water container
Clean liquid waste container
Clean ProCell/CleanCell Compartments
Clean reagent disk and compartment
Empty solid waste
Replace pinch valve tubing (PM visit)
Replace pipettor seals (PM visit)
Replace printer paper
Replace printer ribbon

4.2 Clean S/R Probe

Dirt on the sample/reagent (S/R) probe may cause contamination and carryover, and affect results. Clean this part daily to prevent contamination.

Recommended frequency:	Daily
Operator time:	Approximately 1 minute.
Analyzer time:	None.
Precautions:	The operation switch must be OFF.

**Caution**

DO NOT clean the mixer. Cleaning the mixer may alter the adjustments and cause movement errors.

Materials Required

Gauze squares
Distilled or deionized water
70% isopropyl alcohol

Catalog Number

obtain locally

obtain locally

Procedure

1. Move the S/R probe to an area where you can readily access it.



Caution

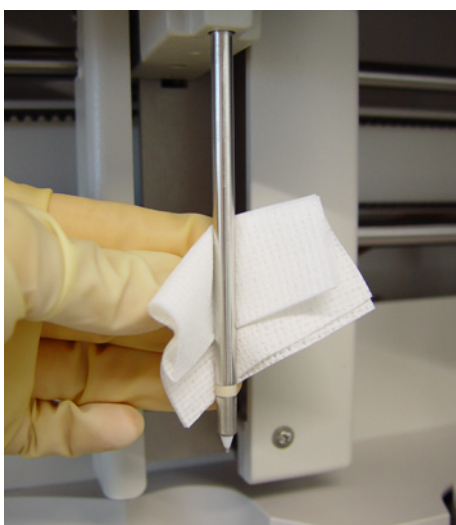
Power must be off to move analyzer components. If power is on, the motors are engaged and attempted movement may damage these components.

2. Wipe the outer surfaces of the S/R probe and probe tip with a gauze square soaked in distilled or deionized water.

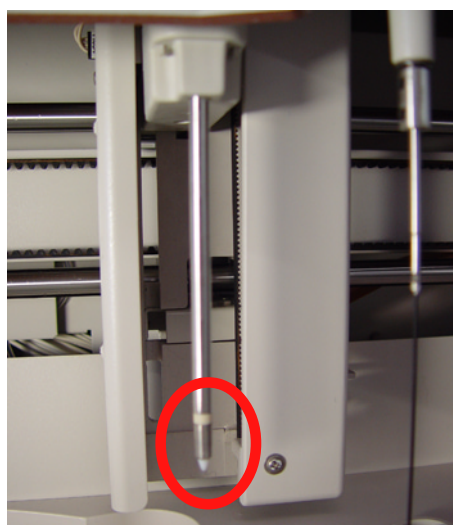


Caution

Do not bend the probe during cleaning! Be careful to not damage the lower end of the S/R probe. See below.



Wipe S/R probe



S/R probe tip

3. If the probe appears dirty, wipe the outer surfaces with a gauze square soaked in 70% isopropyl alcohol. Follow with a gauze square soaked in distilled or deionized water.
4. When you power ON the analyzer, it performs the start-up reset operation, and each mechanism returns to its home or Stand-by position.

4.3 Finalization Maintenance

Finalization is the analyzer status that occurs between the time when the analyzer stops pipetting samples (S. Stop or R. Stop) and Stand-by. Pressing **STOP** when the analyzer status is in S. Stop or R. Stop bypasses finalization and puts the analyzer directly into Stand-by. If the Elecsys 2010 analyzer does not automatically enter finalization status during the course of the day (i.e., continuously loading the analyzer or pressing **STOP**), you must initiate finalization maintenance.

Finalization allows the analyzer to stand unused for several hours (e.g., overnight). The system is primed with water, the measuring cell is filled with ProCell and the sipper probe is cleaned with water.

Recommended frequency:	Daily, if the analyzer does not automatically enter finalization during the course of the day.
Operator time:	Approximately 30 seconds.
Analyzer time:	Approximately 5 minutes.
Precautions:	None.

Procedure

1. Touch the **Utility** folder tab.
2. Touch the **Maintenance** button.
3. Touch the **Finalization Maintenance** button to access the **FINALIZATION MAINTENANCE** pop-up window.
4. Touch **Start**.

4.4 Clean Incubator and Aspiration Station

Spills on the incubator could cause gripper movement alarms. The incubator and aspiration station should be cleaned weekly.

Recommended frequency:	Weekly.
Operator time:	Approximately 5 minutes.
Analyzer time:	None.
Precautions:	The operation switch must be OFF.



Caution

DO NOT use an acid solution or an alkaline solution to clean the system reagent compartment. The compartment is made of aluminum and these solutions degrade the metal.

Materials Required	Catalog Number
Gauze squares	obtain locally
Cotton swabs	obtain locally
Distilled or deionized water	-----

Procedure

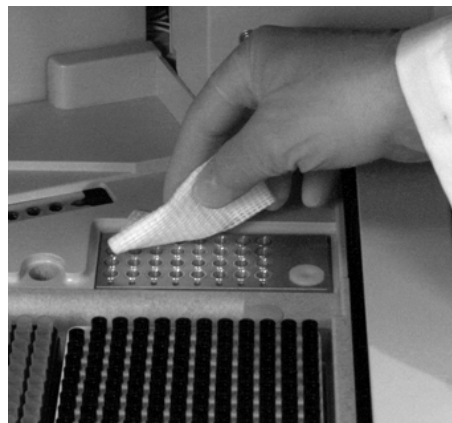
1. Move the S/R arm to the far left and the gripper toward the front of the analyzer. Move the sipper arm to the far right.



Caution

Power must be off in order to move analyzer components. If power is on, the motors are engaged and attempted movement may damage these components.

2. Clean the top of the incubator with gauze squares dampened with distilled or deionized water.
3. If the incubator appears dirty, use a slight scrubbing motion with the water-soaked gauze squares. DO NOT use an acid solution or an alkaline solution to clean the incubator. The incubator is made of aluminum and these solutions degrade the metal.



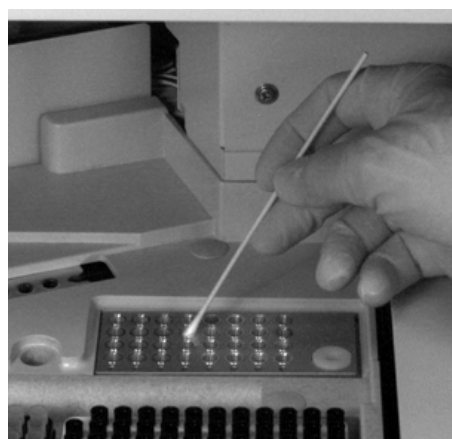
Wipe incubator surface

4. Next, wet a cotton swab with distilled or deionized water and swab each of the 32 positions on the incubator, as well as the aspiration station.
5. Use a dry gauze square to dry the incubator when you are finished cleaning.



Caution

Make sure that the incubator surface and its positions are dry or you may experience gripper problems when you resume operation.



Swab incubator positions

6. When you power ON the analyzer, it performs the start-up reset operation, and each mechanism returns to its home or Stand-by position.

4.5 Clean Sipper Probe

Dirt on the sipper probe may cause contamination and carryover, and affect results. Clean this part weekly to prevent contamination.

Recommended frequency:	Weekly
Operator time:	Approximately 1 minute.
Analyzer time:	None.
Precautions:	The operation switch must be OFF.

Materials Required

Gauze squares
Distilled or deionized water
70% isopropyl alcohol

Catalog Number

obtain locally

obtain locally

Procedure

1. Move the sipper probe to an area where you can readily access it.



Caution

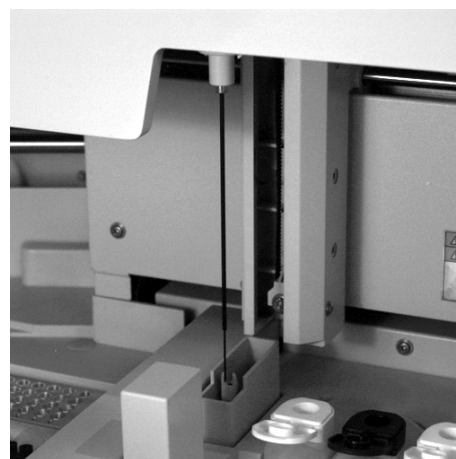
Power must be off to move analyzer components. If power is on, the motors are engaged and attempted movement may damage these components.

2. Wipe the outer surfaces of the sipper probe with a gauze square soaked in 70% isopropyl alcohol. Follow with a gauze square soaked in distilled or deionized water.



Caution

Do not bend the probe during cleaning! Be careful to not damage the lower end of the sipper probe.



Sipper probe

3. When you power ON the analyzer, it performs the start-up reset operation, and each mechanism returns to its home or Stand-by position.

4.6 Clean Rinse Stations for R/S Probe, Mixer and Sipper Probe

Contamination in the rinse stations for the S/R probe, the mixer and the sipper probe can be responsible for carryover. To prevent contamination, clean the rinse stations every two weeks.

Recommended frequency:	Every two weeks.
Operator time:	Approximately 10 minutes.
Analyzer time:	None.
Precautions:	The operation switch must be OFF.



Any component that comes into contact with sample fluids is potentially biohazardous and should be handled in an appropriate manner. Wear protective gloves when handling these materials.

Materials Required

Cotton swabs
70% isopropyl alcohol
Syringe with attached tubing
Distilled or deionized water
(approximately 300 mL)

Catalog Number

obtain locally
obtain locally
obtain locally

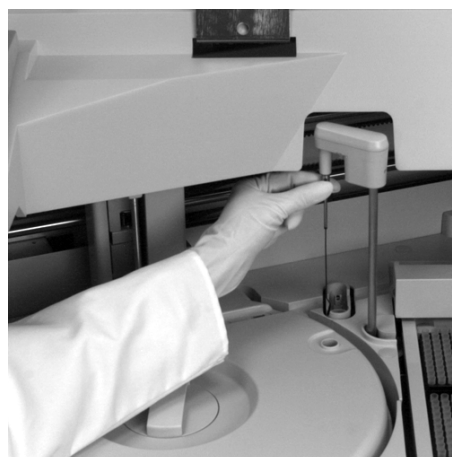
Procedure

1. Move the S/R probe, the mixer and the sipper probe to an area away from the rinse stations.



Caution

Power must be off in order to move analyzer components. If power is on, the motors are engaged and attempted movement may cause damage to these components.



**Move component away
from rinse station**

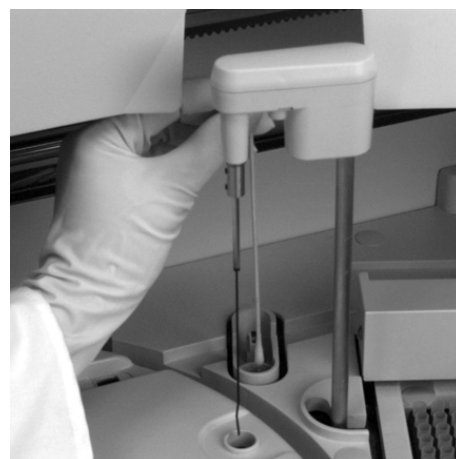
2. Take a syringe with tubing attached to its end (as in the photo on the right) and aspirate the water out of the mixer rinse station.
3. Use a cotton swab soaked in 70% isopropyl alcohol to thoroughly clean the S/R probe, mixer and sipper rinse stations.
4. Take another cotton swab soaked in distilled or deionized water and wipe the rinse stations again.
5. Fill the syringe with distilled or deionized water and refill the mixer rinse station. This should take approximately 50-100 mL of water. Also, flush the S/R probe and sipper rinse stations with water (50-100 mL).
6. Aspirate the water out of the mixer rinse station again using the syringe.
7. Refill the mixer rinse station and flush all the rinse stations with distilled or deionized water one final time.
8. When you power ON the analyzer, it performs the start-up reset operation, and each mechanism returns to its home or Stand-by position.



You may want to use two syringes for this procedure – one for aspirating liquid and the other for refilling the rinse stations.



Aspirate/refill the rinse stations



Swab mixer rinse station

4.7 Perform Liquid Flow Cleaning

Contamination in the sipper system could potentially degrade sample accuracy and precision, or possibly block the measuring cell flowpath. To keep the sipper liquid flowpath clean and maintain the integrity of the measuring cell, perform a liquid flow cleaning every two weeks. High volume analyzers may require more frequent cleaning.

Recommended frequency: Every two weeks or after 2500 - 3000 tests, whichever comes first.

Operator time: Approximately 12 minutes.

Analyzer time: Approximately 16 minutes.

Precautions:



CAUTION. WARNING. CORROSIVE. SysClean causes severe burns. Keep out of reach of children. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention. Remove all contaminated clothing immediately. Wear suitable gloves and eye/face protection.

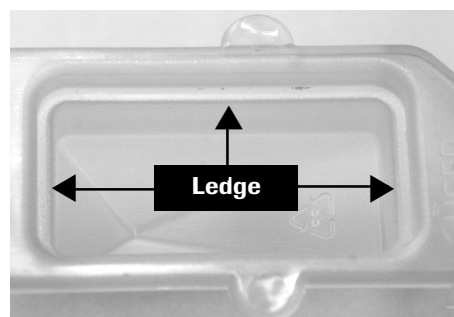
Materials Required

Catalog Number

	US	Non-US
SysClean	1298500	1298500-316
SysClean adapter	1933159	1933159

Pre-Cleaning Steps

1. Remove the ProCell bottle from position 3 of the system reagent compartment.
2. Fill the "USER" compartment (smaller compartment) of the SysClean adapter to the ledge of the compartment with SysClean reagent (approx. 9 mL).



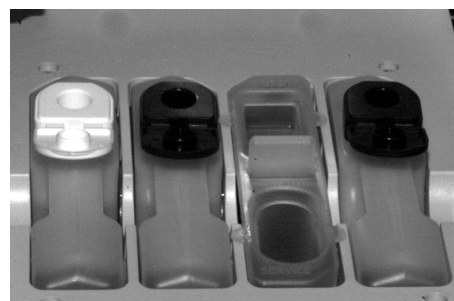
Location of ledge in "USER" compartment of adapter

3. Carefully, insert the filled SysClean adapter into position 3 of the system reagent compartment with the edge marked "USER" facing the back of the analyzer.



Caution

If you spill SysClean reagent on the analyzer, immediately clean the spill with distilled or deionized water.



SysClean adapter in position 3

4. Remove the liquid waste container and thoroughly clean it with distilled or deionized water.

**Warning**

SysClean reagent combined with the contents of the liquid waste container could cause potentially harmful fumes.



If necessary, refer to Section 4.10, Clean Liquid Waste Container, for additional information on cleaning the liquid waste container.

5. Verify ProCell/CleanCell bottles are in positions 1, 2 and 4. Also, verify the bottle lids are open and that there is adequate liquid in the bottles in positions 1 and 2.

Initiate Cleaning

1. Touch the **Utility** folder tab.
2. Touch the **Maintenance** button.
3. Touch the **Liquid Flow Cleaning** button to access the **LIQUID FLOW CLEANING** pop-up window.
4. Touch the Liquid flow cleaning count field.
5. Type "1" and press **ENTER**.
6. Touch **Start**. The pop-up window closes and the system begins cleaning the sipper liquid flowpath.

Post-Cleaning Steps

1. When the analyzer returns to Stand-by, remove the liquid waste container and thoroughly rinse it with distilled or deionized water. Return the liquid waste container to the analyzer.

**Warning**

SysClean reagent combined with the contents of the liquid waste container could cause potentially harmful fumes.



If necessary, refer to Section 4.10, Clean Liquid Waste Container, for additional information on cleaning the liquid waste container.

2. Remove the SysClean adapter and properly discard any remaining SysClean. Thoroughly rinse the adapter.

**Caution**

If you spill SysClean reagent on the analyzer, immediately clean the spill with distilled or deionized water.

3. Return the ProCell bottle to position 3 of the system reagent compartment.

4.8 Cleaning Floppy Disk Drive

Clean the floppy disk drive monthly to optimize the performance of the disk drive.

Recommended frequency:	Monthly.
Operator time:	Approximately 2 minutes.
Analyzer time:	Approximately 30 seconds.
Precautions:	The analyzer must be in Stand-by.

Materials Required	Catalog Number
Disk cleaning kit (dry)	707422200

Procedure

1. Verify the analyzer is in Stand-by.
2. Remove the data disk from the drive and set aside.



Caution

Verify the drive is not active (green light is on) before you remove the data disk.



Caution

Failure to replace the data disk with the cleaning disk results in the LOSS OF ALL DATA ON THE DATA DISK.

3. Touch the **Utility** folder tab.
4. Touch the **Maintenance** button.
5. Touch the button **FDD Cleaning** to access the **FDD CLEANING** pop-up window.
6. Insert the dry cleaning disk in the drive.
7. Touch **Start**.



Each cleaning disk is good for 60 cleanings. After each cleaning procedure, check one box on the disk label. After all the boxes are checked (60 cleanings), use a new cleaning disk.

8. When the analyzer returns to Stand-by, remove the cleaning disk and return the data disk to the drive.

4.9 Clean Distilled Water Container

A contaminated distilled water container can adversely affect analyzer performance. Clean the distilled water container as needed.

Recommended frequency:	As needed.
Operator time:	Approximately 10 minutes.
Analyzer time:	None.
Precautions:	The analyzer must be in Stand-by or turn OFF the operation switch.

Materials Required	Catalog Number
Gauze squares	obtain locally
Cleaning brush	obtain locally
Paper towels	obtain locally
70% isopropyl alcohol	obtain locally

Procedure

1. Raise and remove the distilled water container.
2. Remove the cap and discard any water remaining inside.
3. Rinse the container with water, then follow with distilled or deionized water.
4. If the inside of the container appears dirty or contaminated use a large cleaning brush immersed in 70% isopropyl alcohol to scrub the interior of the container. Rinse thoroughly with distilled or deionized water.



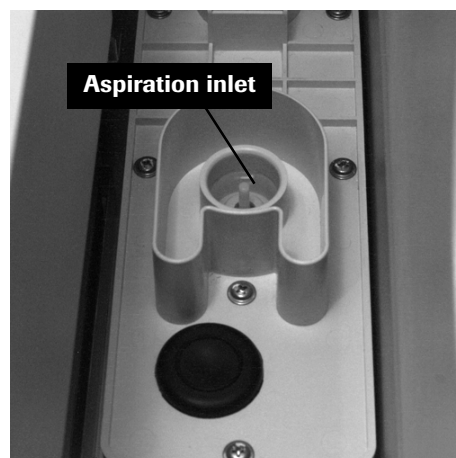
Remove distilled water container

5. Remove the valve on the bottom of the distilled water container.
6. Clean the valve with a wet brush, then rinse with distilled or deionized water. If the valve appears dirty, use a brush immersed in 70% isopropyl alcohol to clean the valve. Then, rinse thoroughly with distilled or deionized water.



Valve

7. Use a gauze square to wipe and clean the aspiration inlet for distilled or deionized water supply, located on the analyzer.
8. Connect the valve on the container bottom and fill the container with distilled or deionized water. Then, dry the outside of the container with paper towels, attach the cap to the container and return the container to the analyzer.



Aspiration inlet

4.10 Clean Liquid Waste Container

A full liquid waste container causes an alarm and interrupts operation. The liquid waste container must be checked and emptied as needed.

Recommended frequency: As needed.

Operator time: Approximately 5 minutes.

Analyzer time: None.

Precautions: The analyzer must be in Stand-by or turn OFF the operation switch. Do not touch the **System Reset** or **Reagent Scan** buttons, or power ON the analyzer while cleaning the liquid waste container.



Any component that comes into contact with sample fluids is potentially biohazardous and should be handled in an appropriate manner. Wear protective gloves when handling these materials.

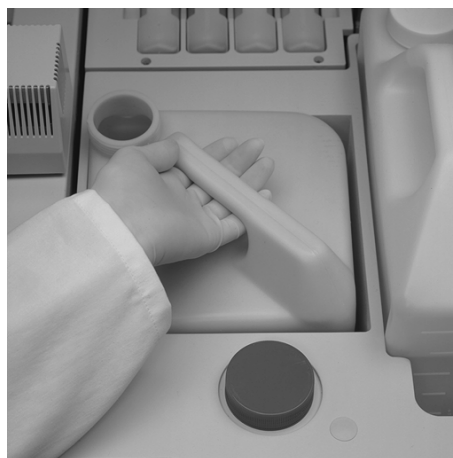
Materials Required

Catalog Number

	US	Non-US
70% isopropyl alcohol	obtain locally	obtain locally
Paper towels	obtain locally	obtain locally
optional - germicidal agent (pH - 9)	obtain locally	READES 2000

Procedure

1. Pull the liquid waste container toward you, cap it and raise it carefully, while avoiding the liquid waste outlet.
2. Place a folded paper towel under the waste outlet to catch any waste droplets that may fall.
3. Empty the container and rinse it thoroughly with water.
4. If the inside of the container appears dirty, use 70% isopropyl alcohol to rinse the container. Follow with a thorough water rinse.
5. Wipe the outside of the container with a paper towel.
6. Use a paper towel to wipe the compartment where the container is to be placed.
7. OPTIONAL – Add the appropriate volume of a germicidal agent with a pH - 9 (as directed in its product labeling) to the liquid waste container.



Remove liquid waste container



Warning

DO NOT USE BLEACH in the liquid waste container. Bleach combined with the contents in the liquid waste could cause potentially harmful fumes.

8. Remove the paper towel under the waste outlet and replace the liquid waste container. Push the container forward so that the container opening is under the liquid waste outlet. Be sure to remove the cap.

4.11 Clean ProCell/CleanCell Compartments

The system reagent compartment should be cleaned as needed to eliminate spills from the ProCell and CleanCell reagents.

Recommended frequency:	As needed.
Operator time:	Approximately 5 minutes.
Analyzer time:	None.
Precautions:	The operation switch must be OFF.



Caution

DO NOT use an acid solution or an alkaline solution to clean the system reagent compartment. The compartment is made of aluminum and these solutions degrade the metal.

Materials Required

Gauze squares
Distilled or deionized water

Catalog Number

obtain locally

Procedure

1. Move the sipper arm as far to the left as the arm will allow.



Caution

Power must be off in order to move analyzer components. If power is ON, the motors are engaged and attempted movement may damage these components.

2. Remove the ProCell and CleanCell reagent bottles.
3. Wipe the inside of the compartments with damp, not wet, gauze squares. DO NOT allow water to pool in the bottom of the compartments. Take care to avoid the photosensors in compartment positions 2 and 3. These sensors check for the presence of the ProCell/CleanCell bottle sets. They appear as rectangular windows located at the back of the compartment, just below the top edge. If you should get the sensors wet, use a cotton swab to dry them.



Wipe ProCell/CleanCell compartments

4. Wipe the compartment with a dry gauze square.
5. Return the ProCell and CleanCell reagents to their respective system reagent compartments.
6. When you power ON the analyzer, it performs the start-up reset operation, and each mechanism returns to its home or Stand-by position.

4.12 Clean Reagent Disk and Compartment

Reagent spills should be cleaned up as they occur. The reagent disk and compartment must be cleaned as needed.

Recommended frequency: As needed.

Operator time: Approximately 15 minutes.

Analyzer time: None.

Precautions: The operation switch must be OFF.



Any component that comes into contact with sample fluids is potentially biohazardous and should be handled in an appropriate manner. Wear protective gloves when handling these materials.

Materials Required

Gauze squares

Distilled or deionized water

70% isopropyl alcohol

Cloth or lint-free towels

Catalog Number

obtain locally

obtain locally

obtain locally

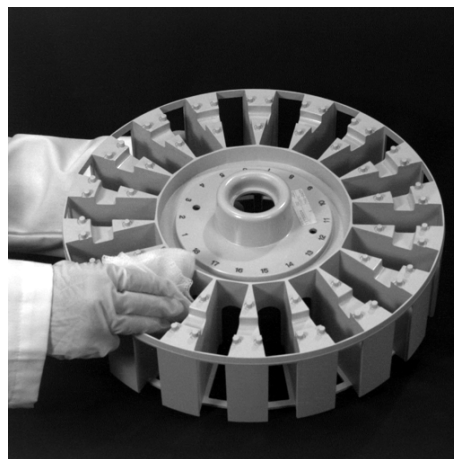
Clean the Reagent Disk

1. Remove the cover from the reagent disk.
2. Loosen and remove the black thumbscrews on the center of the reagent disk.
3. Completely close the reagent pack caps and remove all the reagent packs from the reagent disk.
4. Remove the reagent disk from the compartment.



Loosen and remove thumbscrews

5. Wipe the inside and outside of the reagent disk with gauze squares soaked with distilled or deionized water.
6. If the disk appears dirty, use gauze squares soaked with 70% isopropyl alcohol to clean the disk. Follow with gauze squares soaked with distilled or deionized water.
7. Dry the reagent disk with a cloth or lint-free towels. Set the reagent disk aside.



Clean the inside of the reagent disk

Clean the Reagent Disk Compartment

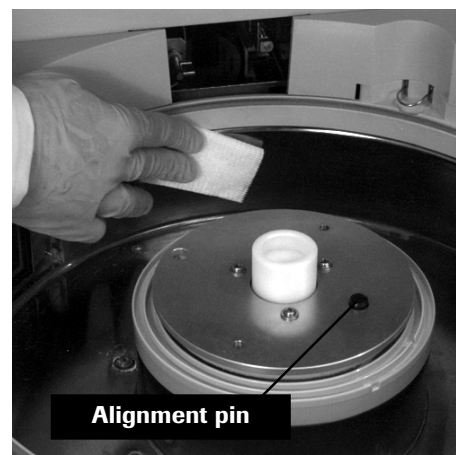
1. Wipe the reagent disk compartment with gauze squares soaked with distilled or deionized water.



Caution

Take care not to scratch or smear the bar code reader window.

2. If the compartment appears dirty, use gauze squares soaked with 70% isopropyl alcohol to clean the compartment. Follow with gauze squares soaked with distilled or deionized water.
3. Dry the reagent disk compartment with a cloth or lint-free towels.
4. Return the reagent disk to the compartment. The disk is keyed; make sure that the alignment pin on the center plate (refer to photo above) is aligned with the hole on the disk.
5. Securely reinstall the thumbscrews.
6. Place the reagent packs back into the reagent disk.
7. Replace the reagent disk cover and lock.



Clean the reagent disk compartment

4.13 Empty Solid Waste

During operation, the solid waste tray is filled with disposed tips and cups. The solid waste tray must be checked and emptied as needed.

Recommended frequency: As needed.

Operator time: Approximately 2 minutes.

Analyzer time: None.

Precautions: The analyzer must be in Stand-by or turn OFF the operation switch. Do not touch the **System Reset** or **Reagent Scan** buttons, or power ON the analyzer while changing the Clean-Liner.



Any component that comes into contact with sample fluids is potentially biohazardous and should be handled in an appropriate manner. Wear protective gloves when handling these materials.

Materials Required

Clean-Liner

Catalog Number

1800507

Procedure

1. Open the door below the tip and cup trays, pull out the tray. Remove and dispose of the Clean-Liner.



Caution

The Clean-Liner has a clear sliding door. Slide the door to close the Clean-Liner.



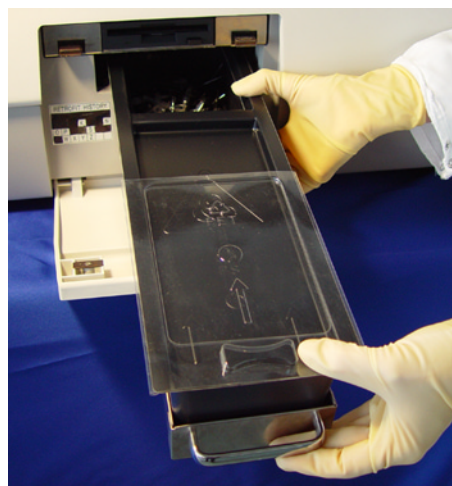
Warning

The Clean-Liner contains potentially biohazardous material. Dispose of the Clean-Liner appropriately.

2. Place a fresh Clean-Liner into the tray. Verify that the sliding door is open and that the opening is located at the back of the tray.
3. Replace the tray in the analyzer and close the door.



The counter for the solid waste resets to "0" when the tray is removed.



4.14 Replace Pinch Valve Tubing (PM Visit)

Worn pinch valve tubing allows liquid to leak, thereby affecting the accuracy of the pipetting volumes and the ability to properly clean the measuring cell. The pinch valve tubing are replaced by your service representative during scheduled preventive maintenance (PM) visits. However, should the tubing require replacement between visits, instructions are provided below.

Recommended frequency: At PM visits or as needed.

Operator time: Approximately 2 minutes.

Analyzer time: Approximately 10 minutes.

Precautions: The operation switch must be OFF while changing the tubing.

Any component that comes into contact with sample fluids is potentially biohazardous and should be handled in an appropriate manner. Wear clean, protective gloves when changing pinch valve tubing.



Materials Required

Pinch valve tubing

Catalog Number

US

741-1610 (2 ea)

Non-US

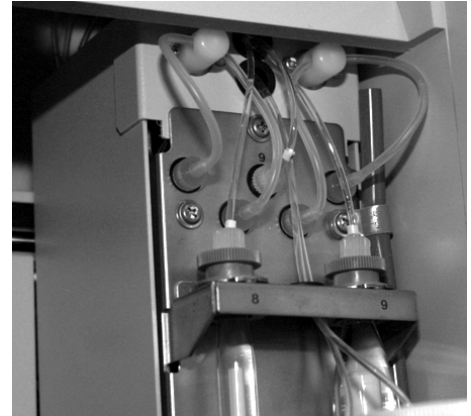
741-1592 (1 m)

Purge the Tubing of Liquid

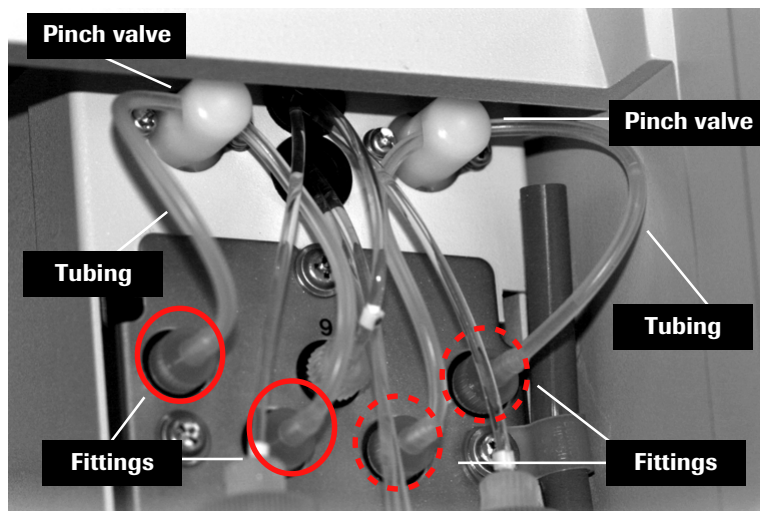
1. Touch **Utility**.
2. Touch **Maintenance**.
3. Touch **M. Cell Exchange** to access the **MEASURING CELL EXCHANGE** pop-up window.
4. Touch **Start**. The tubing is purged of liquid.
5. When the analyzer returns to Stand-by, power it OFF.

Remove the Tubing from the Fittings

The pinch valve tubing and fittings are located above the S/R and sipper pipettors. Refer to the reference point photograph at the right and then to the enlarged view of the area in the photograph below.



Reference point for pinch valve tubing



Enlarged view of pinch valve tubing and fittings

1. Carefully remove the tubing from the fittings on the metal plate.



Warning

There may still be some liquid in the tubing. The liquid that flows through this tubing comes from the measuring cell and is potentially biohazardous. Wear gloves.

2. Remove the tubing from the pinch valve and discard.
3. Take a new piece of tubing and insert it through the pinch valve. Verify the tubing length is 180 mm. If not, cut the tubing to that length.
4. Carefully slide the ends of the tubing over each of the fittings. In the photo on the previous page, one set of fittings is shown with solid red circles and the other pair of fittings is shown with dotted red circles.



Caution

Make sure that you do not damage the fitting when replacing the tubing.

5. Repeat the procedure for the other pinch valve tubing.

Prime the Measuring Cell

1. Power ON the analyzer.
2. Touch **Utility**.
3. Touch **Maintenance**.
4. Touch the **M. Cell Preparation** button to access the **M. CELL PREPARATION** pop-up window.
5. Touch the **M. Cell preparation count** field.
6. Type "10" and press **ENTER**.
7. Touch **Start**. The pop-up window closes and the system begins priming the measuring cell with ProCell. While the system is priming, check for leaks at the fittings and on the tubing.

4.15 Replace Pipettor Seals (PM Visit)

A worn seal piece allows liquid to leak, thereby affecting the accuracy of the pipetting volumes. The seals on the S/R and sipper pipettors are replaced by your service representative during scheduled preventive maintenance (PM) visits. However, should the seals require replacement between visits, instructions are provided below.

Recommended frequency: At PM visits or as needed.

Operator time: Approximately 15 minutes.

Analyzer time: Approximately 5 minutes.

Precautions: The operation switch must be OFF while changing the seals.



Any component that comes into contact with sample fluids is potentially biohazardous and should be handled in an appropriate manner. Wear clean, protective gloves when changing pipettor seals.

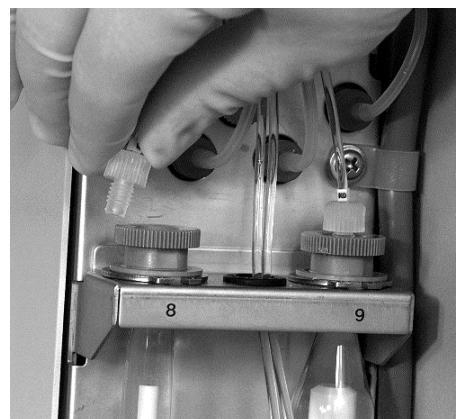
Materials Required

Catalog Number

	US	Non-US
S/R pipettor seal	741-1302	1708716-001
Sipper pipettor seal	741-1303	1708724-001
Spanner wrench	741-0919	1901907-001
Absorbent towels	obtain locally	obtain locally
Gauze squares	obtain locally	obtain locally
Distilled or deionized water	-----	-----
70% isopropyl alcohol	obtain locally	obtain locally

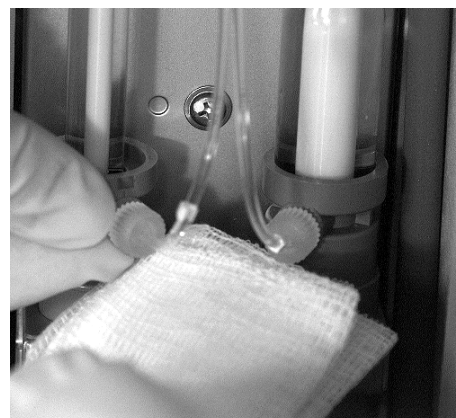
Disassemble Pipettor

1. Disconnect the tubing at the top of the pipettor assembly by turning its retaining nut counterclockwise.



Loosen pipettor retaining nut

2. Hold a dry gauze square or other absorbent material next to the side tubing of the pipettor; disconnect this tubing by turning its retaining nut counterclockwise. Use the gauze square to absorb water as it drains from the tubing.



Disconnect tubing

3. Loosen the knurled locking screw from the top of the pipettor assembly by turning it counterclockwise.



Caution

For the sipper pipettor – loosen and REMOVE the locking screw to prevent damage to the glass barrel.



Loosen knurled locking screw

4. Carefully pull the pipettor assembly out of its mounting block. With one hand, support the glass barrel. With the other hand, grasp the pipettor holder and lift up, then out to remove the assembly. Make sure the plunger is removed from the U-shaped slot.



Avoid touching the top of the glass barrel.

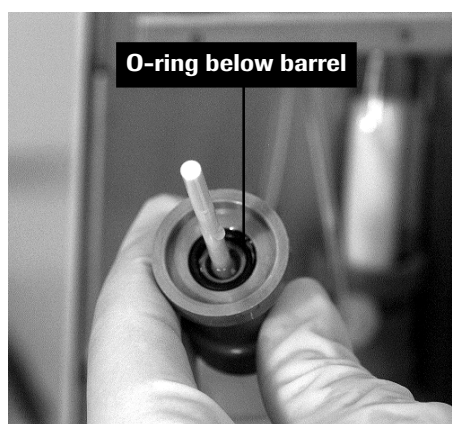


For sipper pipettor – pull the plunger down far enough so that you can lift out the glass barrel. Then remove the remaining pipettor assembly.



Remove pipettor assembly

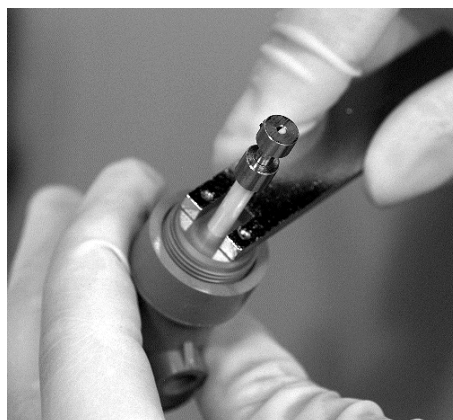
5. Remove the glass pipettor barrel. Set it aside in a safe place. Remove the o-ring that fits below the pipettor barrel and set in a safe place.



Remove o-ring

Expose Pipettor Seal

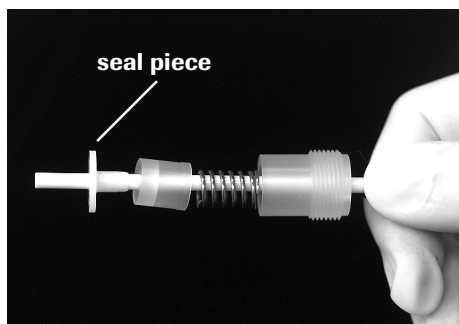
1. Turn the pipettor holder upside down and expose the plunger retaining screw.
2. Apply the spanner wrench to the plunger retaining screw and turn the screw counterclockwise until it is loose.
3. Turn the pipettor holder right side up and carefully lift the pipettor holder off of the plunger. Leave all parts on the plunger.



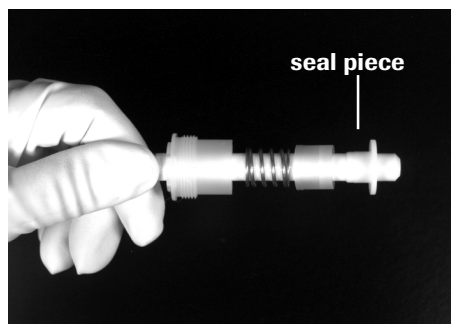
Remove pipettor holder

Replace Pipettor Seal

1. Remove the seal piece, press piece, spring and retaining screw from the plunger. Dispose of the seal piece.
2. Wipe the plunger with a gauze square soaked in 70% isopropyl alcohol to remove any debris. Follow with a gauze square soaked with distilled or deionized water.



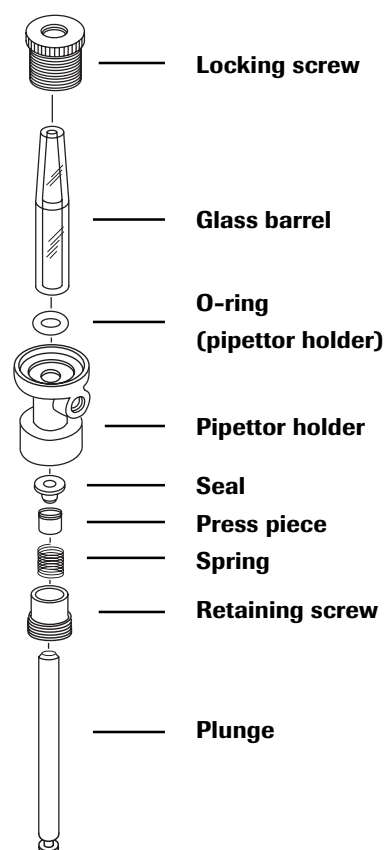
Remove S/R pipettor seal piece



Remove sipper pipettor seal piece

3. Ensure that the retaining screw, spring and press piece are properly positioned on the plunger. Place the new seal on the plunger, verifying the rounded end is down. Refer to the graphic on the right for the correct order of the individual parts.

Although the actual components of the sipper pipettor may not be the same size as those of the S/R pipettor, they are assembled in the same order.

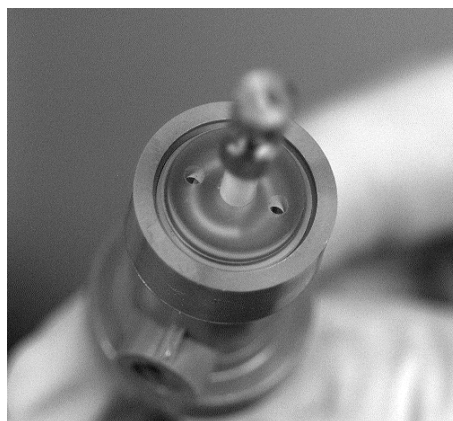


Pipettor assembly order

4. Place the plunger back in the pipettor holder with the pipettor vertically oriented. Tighten the retaining screw with the spanner wrench until the screw is snug with the pipettor holder.

**Caution**

Do not overtighten the pipettor retaining screw.



Tighten retaining screw

Reassemble Pipettor

1. Place the pipettor holder o-ring into the pipettor holder. If the o-ring appears damaged or worn, replace it.
2. Inspect the glass pipettor barrel for chips or cracks at the top and bottom. If the pipettor barrel is etched or damaged in any way, replace it. Place the pipettor barrel over the plunger and onto the pipettor holder. It is easier to place the barrel back on if the barrel and pipettor holder are dry.
3. Return the pipettor holder onto its mounting block by tilting the top of the pipettor toward the instrument. Ensure that the pipettor holder is in the recess on the top surface of the mounting block.

**Caution**

If the pipettor holder is not properly seated in its mounting block recess, damage to the pipettor assembly may occur.

4. The notched (bottom) end of the plunger must be secured within the U-shaped notch of the stepper motor.
5. Rotate the pipettor holder until the side tube port is positioned to accept the pipettor tubing.
6. Finger-tighten the top knurled locking screw. Ensure that the pipettor assembly is seated correctly (not loose or crooked) and the glass barrel o-ring is properly positioned.



Secure plunger in notch

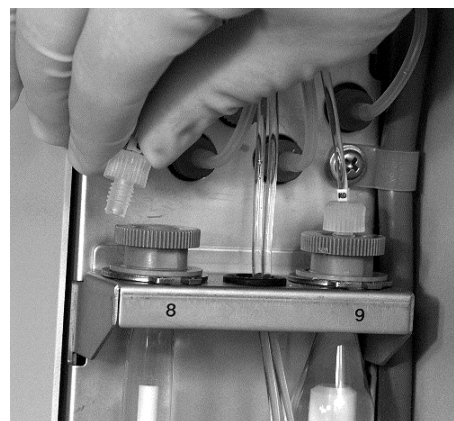
7. Reconnect the pipettor's top tubing and finger-tighten its retaining nut.



Caution

The top and side tubing retaining nuts can be damaged if excessive force is applied when replacing them. Take care not to cross-thread these nuts.

8. Reconnect the side tubing and finger-tighten its retaining nut.
9. Turn the instrument power ON.



Replace retaining nut

Prime the Pipettors

1. Access the **MAINTENANCE** screen after initialization is complete. First touch the **S/R Pipettor Prime** button. This accesses the pop-up window.
2. Touch the priming cycles field, type 10 and press **ENTER**.
3. Touch **Start**. The liquid system is purged of air.
4. During priming, check the pipettor and tubing connections for leaks. The plunger should be in the correct position and must be moving up and down continuously.
5. If air bubbles are found on the plunger, gently tap on the glass barrel to remove the air bubbles. If this is not successful, remove the pipettor and thoroughly clean the plunger again with a gauze square soaked in 70% isopropyl alcohol.
6. Repeat steps 1 - 5, if necessary.
7. When you change the sipper pipettor seal, repeat steps 1 - 6, but touch the **Sipper Pipettor Prime** button instead of **S/R Pipettor Prime**.



The sipper pipettor plunger does not move up and down during a sipper prime.

Prime the Measuring Cell

If you perform a sipper pipettor prime, you must also prime the measuring cell.

1. Touch **Utility**.
2. Touch **Maintenance**.
3. Touch the **M. Cell Preparation** button to access the **M. CELL PREPARATION** pop-up window.
4. Touch the **M. Cell preparation count** field.
5. Type "5" and press **ENTER**.
6. Touch **Start**. The pop-up window closes and the system begins priming the measuring cell with ProCell.

4.16 Other As Needed Maintenance Procedures

There are two other as needed maintenance procedures. They are to replace the printer paper and to replace the printer ribbon.

Replace Printer Paper

For the USA, please refer to the US Supplement for the procedure to replace the printer paper.

For all others, please refer to your printer documentation.

Replace Printer Ribbon

For the USA, please refer to the US Supplement for the procedure to replace the printer ribbon.

For all others, please refer to your printer documentation.

4.17 Extended Power OFF Recommendations

If the 2010 analyzer will not be used for an extended period of time (i.e., > 7 days), contact Technical Support. Different shutdown procedures are recommended depending upon the duration of inactivity. In addition, certain procedures require the assistance of a Roche Diagnostics service representative.

5. Spare Parts

5.1 Spare Parts Overview

The following pages list the catalog number, reference name and common name for each accessory and user replaceable part. The common names have evolved over the course of time and use of the systems and are included for your convenience.

Ordering Information

When ordering replacement parts, please use the catalog number and reference name for each item to ensure that you receive the correct part.

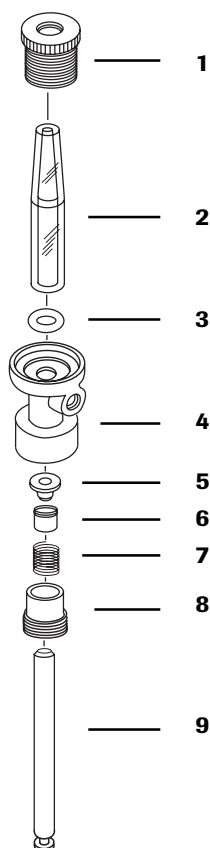
Remember, you are responsible for maintaining an adequate inventory of parts in your accessory kit.

5.2 Accessory and User Replaceable Parts

Sample/Reagent Pipettor

Item	Catalog Number		Reference Name	Common Name
	USA	Non-US		
1	736-3015	0909106	Nut	Locking screw
2	037105600	1701998	Syringe	Glass barrel
3	038012800	0989142	O-ring #P9	O-ring (pipettor holder)
4	736-3029	0990027	Body	Pipettor holder
5	741-0901 *	1708716 *	Seal Spacer P.	Seal
6	741-1304	741-1304	Press Spacer P.	Press piece
7	725186200	1227149	Spring	Spring
8	741-1311	741-1311	Screw P.	Retaining screw
9	741-1300	1708694	Plunger P.	Plunger

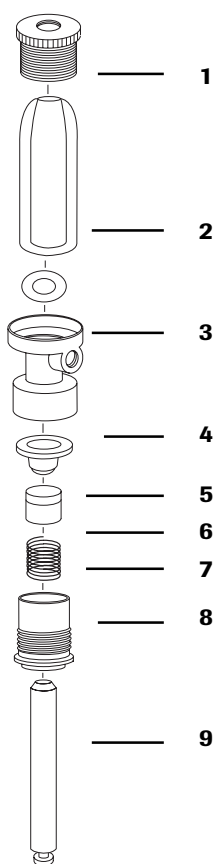
* Part of accessory kit.



Sipper Pipettor

Item	Catalog Number		Reference Name	Common Name
	USA	Non-US		
1	736-3015	0909106	Nut	Locking screw
2	741131300	1809008	Syringe S.	Glass barrel
3	037027600	479128	O-ring #P16	O-ring (pipettor holder)
4	741-1312	741-1312	Body S.	Pipettor holder
5	741-0902 *	1708724 *	Seal Spacer S.	Seal
6	741-1305	741-1305	Press Spacer S.	Press piece
7	741-1307	741-1307	Spring S.	Spring
8	741-1306	741-1306	Screw S.	Retaining screw
9	741130100	1708708	Plunger S.	Plunger

* Part of accessory kit.



Consumables and Accessories

Catalog Number		Reference Name	Common Name
USA	Non-US		
1706799	1706799	Assay Tips	30 x 120 tips
1706802	1706802	Assay Cups	60 x 60 cups
409041	394246	Sample Cups	1000/bag - 500/bag
1776576	1776576	CalSet Vials	2 x 50 vials
1800507	1800507	Clean-Liner	20 liners/box
1707752	1707752	Sample Disk	1 disk
714-3092	714-3092	Sample Tray	1 tray
741-6560	741-6560	Sample racks (5001-5050)	50 racks
741-6561	741-6561	Sample racks (5051-5100)	50 racks
741-6562	741-6562	Sample racks (5101-5150)	50 racks
741-6563	741-6563	Sample racks (5151-5200)	50 racks
741-6564	741-6564	Sample racks (5201-5250)	50 racks
741-6565	741-6565	Sample racks (5251-5300)	50 racks
741-6566	741-6566	Sample racks (5301-5350)	50 racks
741-6567	741-6567	Sample racks (5351-5400)	50 racks
371044	**	Printer paper	2700 sheets/case
900924	**	Printer ribbon	1 ribbon
741-0919 *	1901907 *	Spanner Wrench	1 wrench
1812041	1812041	CapTwist	1 each
707422200	707422200	Dry disk cleaning kit	1 disk
1298500	1298500	SysClean	5 x 100 ml bottles
1933159	1933159	SysClean adapter	1 each

* Part of accessory kit.

** Refer to your specific printer documentation - not available from Roche.

Accessory Kit Contents

Catalog Number		Total Number	Common Name
USA	Non-US		
741-0543	741-0543	1	S/R probe tubing (8)
741-0641	741-0641	1	Sipper probe tubing
741-0803	741-0803	1	S/R pipettor tubing (9)
741-0807	741-0807	1	S/R pipettor tubing (1)
741-0808	741-0808	1	S/R pipettor tubing (2)
741-0809	741-0809	1	Rinse station tubing (7)
741-0901	1708716	1	S/R pipettor seal set (4 seals/set)
741-0902	1708724	1	Sipper pipettor seal set (4 seals/set)
714-0903	1709402	1	S/R probe seal set (2 seals/set)
741-0904	741-0904	1	3.2A fuse set (3 fuses/set)
741-0905	741-0905	1	5.0A fuse set (3 fuses/set)
741-0906	741-0906	1	0.5A fuse set (1 fuse/set)
741-0908	741-0908	1	1.0A fuse set (1 fuse/set)
714-0909	714-0909	1	Sipper probe seal set (2 seals/set)
741-0919	1901907	1	Spanner wrench
741-0966	741-0966	1	Sipper pipettor tubing
741-0969	741-0969	1	Measuring cell tubing
741-1610	741-1610	2	Pinch valve tubing
741-1775	741-1775	1	S/R probe tubing (465)
741-1778	741-1778	1	S/R probe tubing (510)

**Elecsys 2010
Tutorial Guide**

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1. Overview

1.1 Overview of Options

This Tutorial Guide contains quick reference procedures for operating the Roche Diagnostics Elecsys 2010 Immunoassay Analyzer. This Tutorial Guide can be used for training purposes. More detailed information can be found in the Reference Guide, Software Guide and User's Guide.

In the Tutorial Guide, you will find:

- daily operating procedures in step by step format (Chapter 2)
- daily maintenance procedures (Chapter 2)
- tips and quick references to further subjects (How To ... Chapter 3)

Differences in routine handling on the different systems (i.e., disk or rack system) are denoted by the chapter heading, e.g., "2.6 Routine Sample Measurement – Disk System" or by icons within the chapter:



Applies to disk system only



Applies to rack system only

2. Daily Operation

2.1 Power ON

Before processing any samples, you must check for the presence of the data disk, power ON the external printer and analyzer, and log on to the software with your operator ID. The data disk must not be removed.

Check Data Disk

Check that the data disk is in the disk drive by opening the door on the front panel. The data disk must not be removed.



Check data disk

Power the Printer ON

The power switch is located on the front right of the printer. If the printer is not already on, power it on. Check your printer paper supply and make sure it is adequate.



Printer type may vary by country. Please refer to the appropriate printer documentation for details.



Printer ON/OFF switch location

Power the Analyzer ON

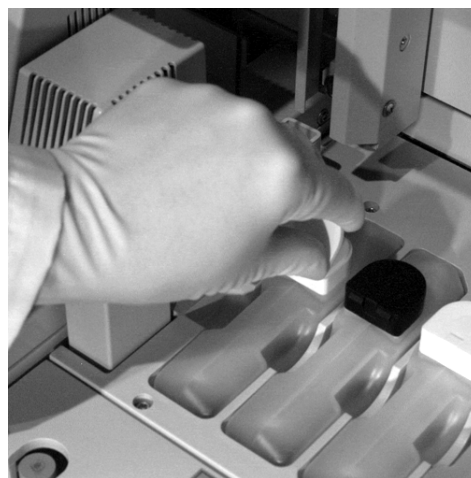
The analyzer is powered ON/OFF by the operation switch located on the front panel.

A small green light on the switch is illuminated when the system is ON.

After powering ON the analyzer, open the lids on the ProCell and CleanCell bottles.



Operation ON/OFF switch location



Open lids of ProCell/CleanCell



The analyzer should always be kept powered on via the circuit breaker.

Log On

After a short period of time, the last screen the software was in when the analyzer was turned OFF appears on the touchscreen.



If the screen remains black when you switch on the analyzer, check if the circuit breaker is OFF. If the analyzer was powered OFF at the circuit breaker, the introductory screen appears after you power ON the analyzer.

Use the following procedure to enter your operator ID number.

- 1 Touch the **Status** tab to open the **STATUS** screen shown below for the disk system. The **Operator ID** field remains in the same place on the screen regardless of which system is used.

The screenshot shows the STATUS screen with a blue background. At the top, there is a navigation bar with tabs: Stand-by, Inventory, Orders, Results, QC, Status (highlighted), and Utility. The top right corner displays 'Operator ID: 47' and '13:00'. Below the navigation bar, the title 'Sample Disk Status' is centered. On the left, there is a 6x5 grid of 30 sample slots, each labeled with a number (1-30) and the word 'Empty'. On the right, there are three fields: 'Operator ID' with a red circle around the value '47', 'Disk No.' with the value '1', and 'Last result at' which is empty. At the bottom right, there are two buttons: 'Sample Scan' (pink) and 'Open Requests' (green).

1	2	3	4	5
Empty	Empty	Empty	Empty	Empty
6	7	8	9	10
Empty	Empty	Empty	Empty	Empty
11	12	13	14	15
Empty	Empty	Empty	Empty	Empty
16	17	18	19	20
Empty	Empty	Empty	Empty	Empty
21	22	23	24	25
Empty	Empty	Empty	Empty	Empty
26	27	28	29	30
Empty	Empty	Empty	Empty	Empty

Operator ID : 47

Disk No. : 1

Last result at :

Sample Scan

Open Requests

- 2 Touch the **Operator ID** field. Type in your identification number. Use a number from 1 - 99.
- 3 Press to confirm.

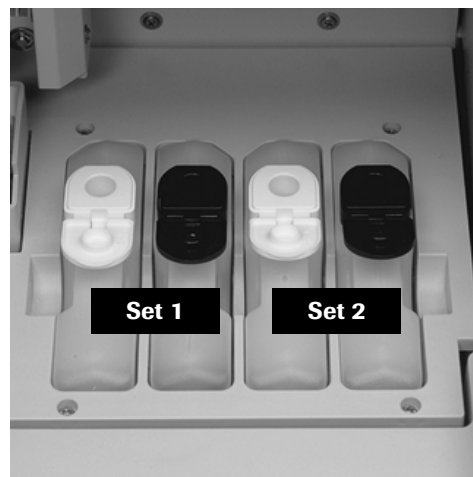
2.2 Inventory Checks

- You should make the following inventory checks before processing samples for the day:
 - probes are in good condition and not dirty
 - tubing is not pinched or bent
 - pipettors are free of bubbles. If bubbles exist, prime the appropriate pipettor.
 - all surfaces in the area of the pipetting station and incubator are clean and free of debris. Liquid spilled on the pipetting station or incubator could cause tips or cups to stick, thereby potentially cause gripper alarms.
- Touch the **Inventory** tab to open the **INVENTORY** screen. The information displayed informs you about the level of consumable materials.
- If levels of consumable materials are low, carry out the following steps as needed. If sufficient consumer materials are available, move on to the subsection "Prepare Calibrators and Controls".

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
TSH 0 150 6	C M T4 1 180 1	M T3 0 80 4	RC HCGSTAT 0 100 2	R HCGSTAT 0 100 3	
CEA 1 E 0 12	AFP 1 70 5	PSA 1 84 13	FERR 0 64 14	FERR 0 94 15	
B12 0 X 25 7	P-B12 X 25 8	FOL 0 N 90 9	DIG 0 T 18 10	DIG 0 88 11	
		Dil Uni 18 16	Cups 100	Tips 360	
Set 1 Set 2 100% 75%	System Water	Liquid Waste	Solid Waste 507	Reagent Scan	

Check System Reagents

Replace ProCell and CleanCell as needed. The system reagent button is green if Set 1 and Set 2 are $> 30\%$. The button is yellow if Set 1 and Set 2 are $> 0\%$ and $< 30\%$. The button is red if Set 1 and Set 2 are 0% .



Check ProCell and CleanCell

To check the level in a system reagent bottle set, touch the Set 1 Set 2 button. This opens the **SYSTEM REAGENT DETAILS** pop-up window and displays the percentages of reagent in each bottle. In this window you can enter the ProCell lot number. This lot number is then printed on the **INVENTORY** report.

Stand-by		Operator ID: 47 07:40																							
Inventory	Orders	Results	QC	Status	Utility																				
TSH 0 150 6	C T4 18	System Reagent Details <table border="1"> <thead> <tr> <th colspan="2">Set 1</th> <th colspan="2">Set 2</th> </tr> <tr> <th>PC</th> <th>CC</th> <th>PC</th> <th>CC</th> </tr> </thead> <tbody> <tr> <td>100%</td> <td>100%</td> <td>75%</td> <td>78%</td> </tr> <tr> <td colspan="2">Lot No. of PC 67400701</td> <td colspan="2">Lot No. of PC 67400701</td> </tr> <tr> <td colspan="2">OK</td> <td colspan="2">Cancel</td> </tr> </tbody> </table>		Set 1		Set 2		PC	CC	PC	CC	100%	100%	75%	78%	Lot No. of PC 67400701		Lot No. of PC 67400701		OK		Cancel		2	R HCGSTAT 0 100 3
Set 1				Set 2																					
PC	CC			PC	CC																				
100%	100%			75%	78%																				
Lot No. of PC 67400701				Lot No. of PC 67400701																					
OK		Cancel																							
CEA 1 0 12	E AF 70	14	FERR 0 94 15																						
B12 0 25 7	X P- 25	10	DIG 0 88 11																						
			Tips 360																						
Set 1 Set 2 100% 75%	System Water	Liquid Waste	Solid Waste 507	Reagent Scan																					

There are photosensors located in positions 2 and 3 of the system reagent compartment. If you remove a bottle from one of the positions containing a photosensor and the volume in that bottle is 100%, the analyzer considers that bottle set to be a new bottle set even if the bottle has been on the analyzer for several hours or days. The analyzer waits 15 minutes for temperature equilibration before using what it considers a "new" bottle set.



System reagent position

If you must load two new bottle sets of ProCell/CleanCell, then load these new bottles as your first inventory check. Therefore, by the time you are ready to begin operation, the system reagents should be at temperature. If they are not, you will receive ProCell/CleanCell reagent temperature alarms. For further information on these alarms, please refer to chapter 3, Instrument Alarms, in the User's Guide.



The bottles on the right (Set 2) are consumed first. If replacing the bottles on the right, move the bottles from the left (Set 1) to the right. Then load the new bottles in positions 1 and 2.

Check System Water Container

If the **System Water** button is red, the container is empty. Fill the container with system water, add SysWash and return the container to the analyzer. SysWash has to be used with a dilution 1+100. The stability after opening is 3 months, on the Elecsys system 2 weeks. Clean the container if it appears dirty or contaminated. For detailed instructions, please refer to chapter 4, Maintenance, in the User's Guide.



Check system water container

Check Liquid Waste Container

If the **Liquid Waste** button on the screen is red, the waste container needs to be emptied. Treat the waste from the waste container as potentially infectious. You may add an appropriate volume of a germicidal agent (as directed in its product labeling) to the empty liquid waste container before processing samples. Return the container to the analyzer. Make sure that you remove the blue lid from the container.



Caution

Do **not** use bleach or strong alkaline disinfectants (Ph > 9.5) in the liquid waste container. This, combined with the contents in the liquid waste, could cause potentially harmful fumes. Be aware that the contents of the liquid waste container are potentially infectious.



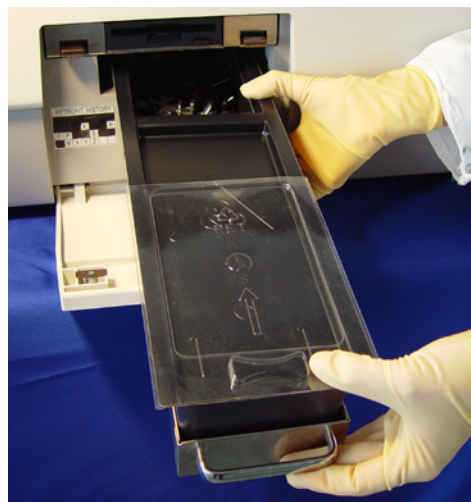
Empty liquid waste container

Clean the container if it appears dirty or contaminated. For detailed instructions, please refer to chapter 4, Maintenance, in the User's Guide.

Check Solid Waste Tray


The **Solid Waste** button turns red when the count reaches 1100. Check the solid waste tray and replace with a new Clean-Liner. Make sure that the opening of the Clean-Liner is facing towards the back of the analyzer and that the sliding door on the liner is open.

The software counts the tips and cups used during the course of operation. When the analyzer senses that the solid waste tray was removed, the counter resets to 0 (zero). Therefore, we recommend that if you remove the solid waste tray you should also discard the solid waste or replace the Clean-Liner at the same time.

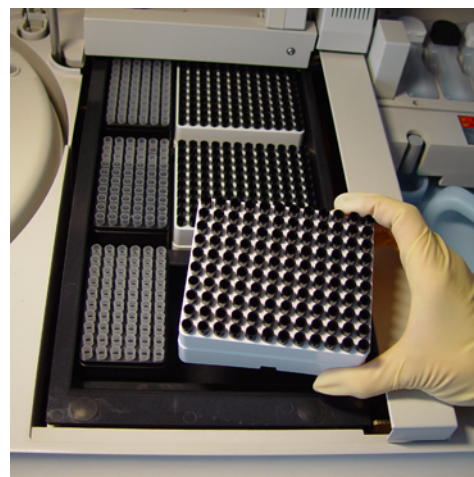


Check solid waste tray

Check Assay Cups and Tips

The  button turns yellow when the count is < 60 cups. The Tip button turns yellow when the count is < 120 tips. The button(s) turn red when the cup or tip count is 0 (zero). Replenish the analyzer with new cup or tip trays, if necessary. **Do not add or remove single tips or cups from the trays.**

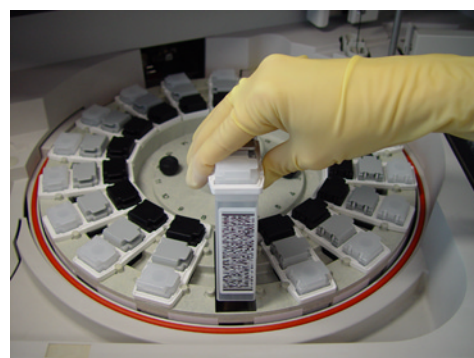
Make sure the trays are seated properly. The trays are keyed and should fit securely on the analyzer.



Load new cup or tip trays

Load New Reagents

Tests, pretreatments and diluents can be loaded in any combinations with the exception of the following restrictions: At the same time not more than 15 tests, 9 pretreatments or 8 diluents. If you plan to run assays that currently are not stored on the analyzer (as reflected by the **INVENTORY** screen), you must allow them to reach reagent disk temperature (20 ± 3 °C) before starting analysis. Bring cooled reagents to approx. 20 °C and place them on the reagent disk of the analyzer. Reagents on the reagent disk are stored in temperature controlled conditions. No additional time is required if all assays to be performed are stored on the reagent disk. If new reagents were loaded, be sure to close the reagent disk cover. The analyzer will not operate without the cover on the disk.



Load new reagents, if necessary

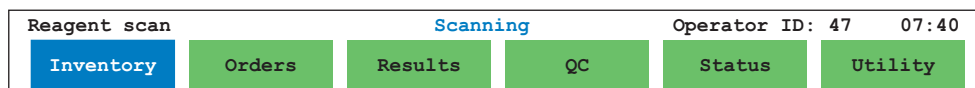
	E
CEA 1	
0	12

If the **INVENTORY** screen displays a red test button with the letter **E**, it means that the reagent pack is empty and you should place a new reagent pack on the disk.



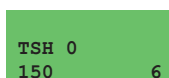
If you remove a reagent pack from the reagent disk, be sure to securely snap the lids closed before returning the pack to refrigerated storage.

If you added or removed a reagent from the reagent disk, close the cover and touch the button Reagent Scan in the **INVENTORY** screen. The scan updates the inventory on the analyzer. During the reagent scan the status line at the top of the screen flashes Scanning. Please refer to the status line below.



Status line during a reagent scan

When the scan is complete, the **INVENTORY** screen indicates the status of each reagent pack on the reagent disk.



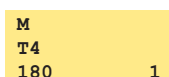
A green test button indicates that a valid calibration exists.



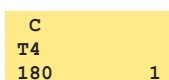
A yellow test button displaying **RC** and red text means that the system requests an L-Cal for this test. If there is more than one reagent pack of a single lot on the reagent disk, only the reagent pack to be calibrated according to automatic calibration displays **RC**. This calibration can be changed in the assay **REAGENT DETAILS** pop-up window.



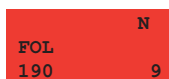
A yellow test button displaying an **R** and red text means that a new reagent pack with no L-Cal is available. Another reagent pack for the assay was prioritized by the system for L-Cal, or you have manually deselected the L-Cal (i.e., the test button previously displayed **RC**).



A yellow test button displaying **M** and black text means that a control has been manually requested for this reagent pack in the **REAGENT DETAILS** pop-up window. This function overrides the settings made in the **CONTROL DEFINITIONS** screen (**UTILITY** folder).



A yellow test button displaying a **C** and black text means that the calibration for the assay was manually requested in **REAGENT DETAILS** or that the daily calibration has expired. (Daily calibration applies to qualitative assays only).



A red test button displaying an **N** and black text means that the corresponding pretreatment or diluent reagent pack is missing from the reagent disk; the test cannot be calibrated.

DIG	T
18	106

A yellow test button displaying a **T** and black text means that the minimum available tests threshold for the assay has been reached. The threshold is defined in the **TEST CONDITIONS DETAILS** pop-up window/**TEST CONDITIONS** screen (**UTILITY** folder).

B12	X
25	7

Any test button displaying an **X** means that the reagent pack is expired. The analyzer can only generate a reagent pack calibration (R-Cal). Results are flagged with the data alarm 52: Expired reagent pack. Reagent stability recommendations are specified in the package insert.

C H	
T4 1	
180	1

A yellow button displaying **C M** and black text means that a calibration and a control has been manually requested for this assay in the **REAGENT DETAILS** pop-up window.

What's Next?

When you have completed the inventory checks, proceed to chapter 2.3, Delete Open Requests, if necessary or chapter 2.4, Initiate Calibration/Control Measurement.

2.3 Delete Open Requests

Open requests represent sample orders not yet processed. Delete open requests as necessary if unprocessed requests exist in the system. Follow the procedure below to delete all open requests in the system.



You can only delete open requests when the system is in Stand-by.



- 1 Touch the **Status** tab to open the **STATUS** folder.
- 2 Touch the **Disk No.** field, type the disk number (0-9) for which you wish to delete open requests and confirm.

The screenshot shows the 'STATUS' folder interface. At the top, there are tabs: Inventory, Orders, Results, QC, Status (selected), and Utility. The top right corner displays 'Operator ID: 47' and '14:00'. Below the tabs is a 'Sample Disk Status' section with a grid of 30 disks. The status of each disk is shown in a colored box: 1-10 are 'Compl' (white), 11-13 are 'Compl' (white), 14 is 'Incomp' (yellow), 15 is 'Compl' (white), 16-18 are 'Compl' (white), 19 is 'Proc' (blue), 20-24 are 'Proc' (blue), 25 is 'Smpl' (pink), 26-27 are 'Occup' (blue), 28 is 'Stop' (red), 29-30 are 'Empty' (green). A pink pop-up window titled 'Open Requests' is displayed in the center, showing 'Number of open reqs.: 35' and buttons for 'Delete Open' and 'Cancel'. To the right of the pop-up, there are fields for 'ID : 47', ' : 1', and 'lt at : 13:46'. At the bottom right, there are buttons for 'Sample Scan' and 'Open Requests'.

- 3 Touch **Open Requests** button to open the **OPEN REQUESTS** pop-up window.
- 4 Touch the **Delete Open** button to delete any open requests.
- 5 Repeat steps 2 - 4 for each sample disk



In single disk mode and on rack systems, only steps 1, 3, and 4 need to be followed.

What's Next?

When you have completed data management, proceed to chapter 2.4, Initiate Calibration/Control Measurement to calibrate the analyzer.

2.4 Initiate Calibration/Control Measurement

Calibrate any reagent packs based on information indicated in the **INVENTORY** screen or the **REAGENT DETAILS** pop-up window.

Prepare Calibrators and Controls

Based on the reagent scan just performed, prepare calibrators, if necessary. Not all calibrators require reconstitution; most are ready to use. Refer to the specific calibrator package insert. Prepare controls, if necessary. Follow instructions on the appropriate package insert.

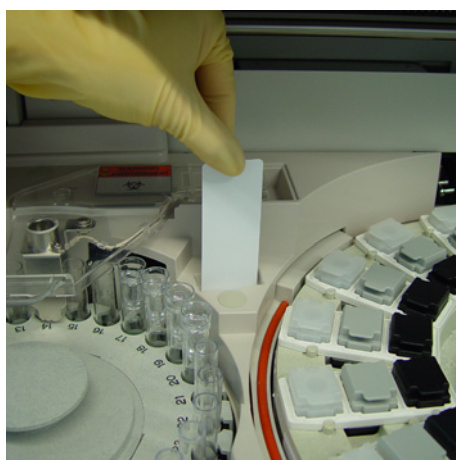


Always use immunoassay controls and calibrators at room temperature. Allow adequate time for all calibrators and controls to reach room temperature before processing samples. Remember that the calibrator stability varies at room temperature. Do not leave the calibrators out at room temperature too long. Close the lids on the CalSet vials when not in use to prevent evaporation. Check the package insert for details.

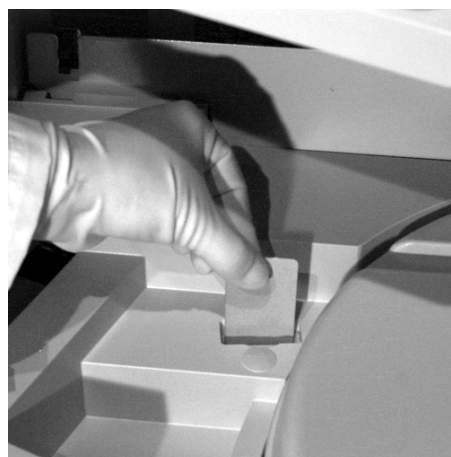
Perform Bar Code Card Scan

Perform a bar code card scan if a new lot of calibrators or controls is used. Follow the procedure below.

- 1 Touch the **Utility** tab to open the **UTILITY** screen.
- 2 Touch either the **Calibration Data** or the **Control Definition** button.



Insert bar code card into station (Disk)



Insert bar code card into station (Rack)

- 3 Insert the calibrator or control bar code card into the card reading station according to your system (refer to the photos above). The bar code must face toward the back of the analyzer. Push the card as far down as it will go into the station.
- 4 Touch the **BC Card Scan** button to initiate the scan. The status line changes as follows:

BC card scan		Scanning		Operator ID: 47		07:40
Inventory	Orders	Results	QC	Status	Utility	

The bar code card was successfully scanned when you hear the bar code reader beep. Do not remove the card until the analyzer returns to Stand-by.

- 5 Repeat steps 2 - 4 for each card to be scanned.



If you are working with a new control lot, remember to activate the tests in **UTILITY/CONTROL DEFINITION**. When using a new lot of a control that is already stored, activated tests will be kept.

Load the Sample Disk/Racks and Program Calibration

Place one set (Cal 1 and Cal 2) of open, bar code-labeled calibrator vials on the sample disk/rack. When the calibrator bar code is scanned by the bar code reader, calibration is automatically requested for the assay.



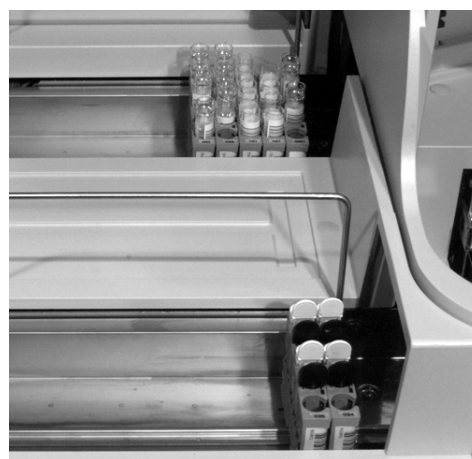
Both levels of an assay's calibrators must be next to each other on the sample disk.



Load the sample disk

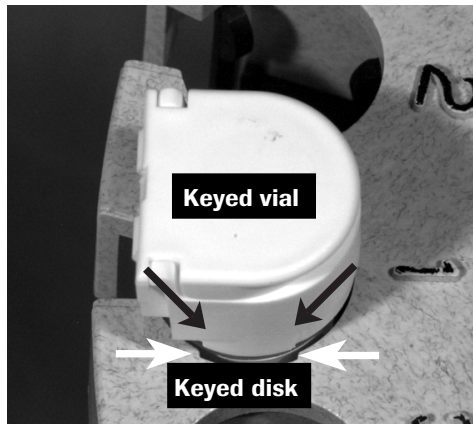


Both levels of an assay's calibrators must be next to each other on the sample rack. Do not split a calibrator set between racks.



Load the sample rack

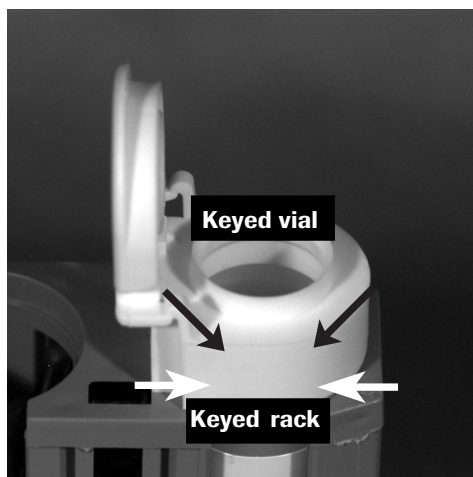
The CalSet vials, control vials and the sample disk are keyed so that the vials are placed on the disk/rack correctly (i.e., with the bar code facing outward and lid straight up). Refer to the photos below.



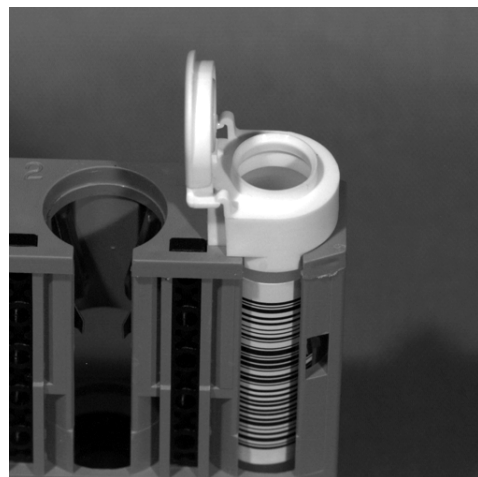
Keyed vial and sample disk



Loaded vial on sample disk



Close up of loaded vial on sample rack



Loaded vial on sample rack

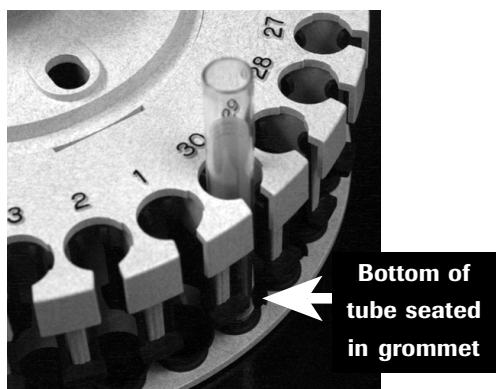
The bar code faces outward, the vial must be opened.

Placement of 13 mm Sample Tubes

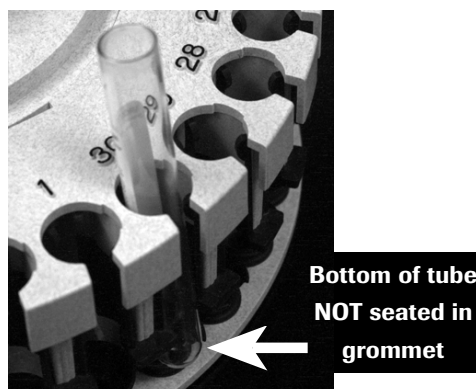
If using 13 mm tubes take special care to correctly place them onto the analyzer. If the bottoms of the tubes are not correctly seated in the grommet at the base of the sample disk or in a rack, the tubes will sit incorrectly. This will cause the S/R probe may attempt to sample outside of the tube, leading to errors and incorrect results. The photos illustrate the problem.



Correct placement on the disk



Correct placement of tube



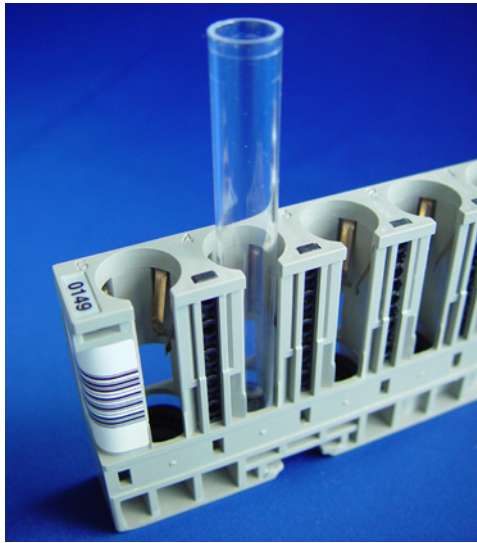
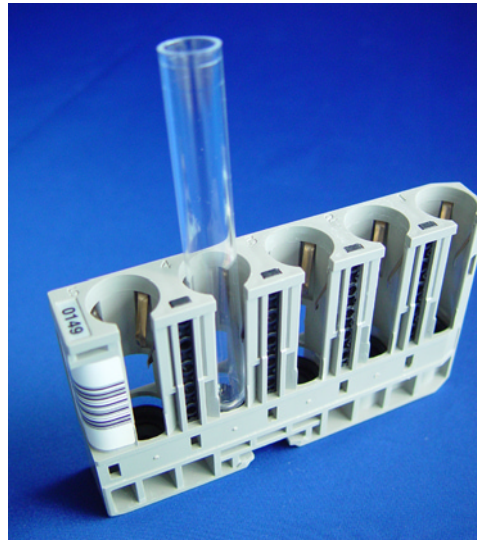
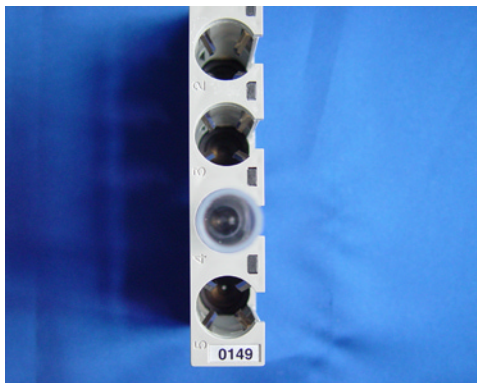
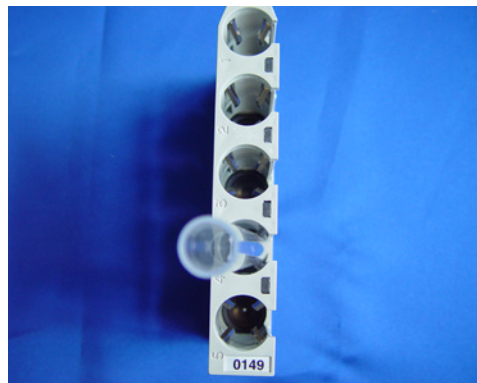
Incorrect placement of tube



**Correct placement of tube
(overhead view)**



**Incorrect placement of tube
(overhead view)**

**Correct placement in a rack****Correct placement of tube****Incorrect placement of tube****Correct placement of tube
(overhead view)****Incorrect placement of tube
(overhead view)****Loading Sample Tubes on the Sample Rack**

When loading primary or secondary sample tubes on sample racks, verify that the tubes are straight in the racks and that any bar codes are visible through the openings on the rack so the bar code reader scans them properly.

Loading Sample Tubes on the Sample Disk

When loading primary or secondary sample tubes on the sample disk, verify that the tubes are straight in their positions and that any bar codes are visible so the bar code reader scans them properly.



Please check always that there is no foam on the samples surface.

Test Selection and Orders for Roche Controls

Roche Diagnostic controls are bar coded. All target values and control ranges for the tests are scanned in from the bar code. Once the bar code information has been scanned-in, the tests for which these controls are valid are automatically displayed in the **CONTROL DEFINITION** screen (**UTILITY** folder). The activated Tests (**UTILITY/CONTROL DEFINITION**) for the controls are automatically measured.

You can find more detailed information in chapter 3, How To Define Roche (Bar coded) Controls and How To Order a Control for a Particular Reagent Pack.



Should a bar code be defective (cannot be scanned), then the respective control must be manually ordered. Manual ordering of controls is described below in Test Selection and Orders for Non-Roche Controls.

Test Selection and Orders for Non-Roche Controls

Non-Roche controls must be manually defined in the **CONTROL DEFINITION** screen (**UTILITY** folder), where the tests are also assigned to the controls. You can find more detailed information in chapter 3, How To Define Non-Roche (Non-Bar coded) Controls.

- 1 Touch the **Orders** tab to open the **ORDERS** screen.
- 2 Touch the **Sample Control Calibrator** button to toggle to the **Control** field (highlights blue). The **Sample ID** field changes to **Control ID**.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
Control ID :	<input type="text"/>	Pre-dil. Off	Sample Control Calibrator		
Sequence No. :	200	Select Control	Dilution Factor		
Rack ID - Pos. :	-	Position Search	Sample Cup Normal	Register	
Sample volume :	ul				
TSH 0	T4 1	T3 0	HCGSTAT 0	CEA 1	
AFP 1	PSA 1	FERR 0	B12 0	P-B12	
FOL 0	DIG 0				

- 3 Touch the **Select Control** button to open the **SELECT CONTROL** pop-up window.

Stand-by Operator ID: 47 07:40

Inventory Orders Results QC Status Utility

Control ID : Pre-dil. Off Sample

PC TM1 152877	PC TM2 152878	PC CARD1 156415	PC CARD2 156416	PC U1 153688
PC U2 153692	PC TSH 153511	Control G 198547	Control H 198548	Control I 198549
			OK	Cancel

- 4 Touch the appropriate button to select a control. The button turns light blue when selected.
- 5 Touch the **OK** button to confirm your selection and return to the **ORDERS** screen. Now, the available assays that were previously defined in **UTILITY/CONTROL DEFINITION** screen are selected.
- 6 Touch test buttons to deselect activated assays, if necessary.

Stand-by Operator ID: 47 07:40

Inventory Orders Results QC Status Utility

Control ID : Control G Pre-dil. Off Sample

Sequence No. : 200 Select Control Dilution Factor Control Calibrator

Rack ID - Pos. : 1 - 15 Position Search Sample Cup Normal Register

Sample volume : 95 ul

TSH 0	T4 1	T3 0	HCGSTAT 0	CEA 1
AFP 1	PSA 1	FERR 0	B12 0	P-B12
FOL 0	DIG 0			



- 7 If you are running in the single disk mode, touch the second **Pos.** field, type the sample disk position (1-30) and press
- 8 If you are running in the multiple disk mode, touch the first **Disk-Pos.** field. Type a disk number (0-9) and press .



- 7 Touch the **Rack Pos.** field. Type the rack position and press .
- 8 Touch the **Rack ID** field. Type the rack number and press .



9 Touch the **Register** button to register test selections.

- The cursor returns to the **Sample ID** field.
- The **Sequence No.** increases.
- The **Disk-Pos.** increases.

10 Repeat steps 2 - 9 until all controls are programmed.

11 Load Stop bar code.




9 Touch the **Register** button to register test selections.

- The cursor returns to the **Sample ID** field.
- The **Sequence No.** increases.
- For rack positions 1 - 4, the **Rack Pos.** increases.
- For position 5, the **Rack Pos.** returns to 1.
- For rack position 1 - 5, the **Rack ID** remains unchanged.
- After position 5 has been entered, the **Rack ID** clears.

Print a Work List (Optional)

After programming your controls, you can print a work list of all positions on the sample disk. Print the work list by pressing the d key while in the **ORDERS** screen. For details on the work list, please refer to chapter 8, Reports, in the Software Guide.

Initiate Operation

Press the  key to initiate operation.



Be sure to remove calibrators and controls from the sample disk when sampling is complete. Close the lids and return them to the refrigerator.

What's Next?

When your calibration is complete, proceed to chapter 2.5 Calibration Validation, to evaluate your calibration.

2.5 Calibration Validation

Calibration results are printed automatically once calibration is completed if automatic printing is selected in the **DOCUMENTATION SETUP** screen (**UTILITY** folder). Duplicate count readings of the first and second calibrators are printed as in the example below. The status of the calibration can be checked on the **CALIBRATION DATA** screen, in the **CALIBRATION DATA DETAILS** pop-up window (**UTILITY** folder) or on the **CALIBRATION DATA** report.

Calibration Data		Operator ID: 02	02/27/2002 13:35

Lot calibration was successful			
Test code	:	LH 0	
Unit	:	IU/l	
Lot no. reagent pack	:	195772	
Reagent pack number	:	7889	
Exp. date reagent pack	:	03/2002	
Lot Calibration			
Lot calibration date	:	02/27/2002	
Reagent pack no. for Lot Calib.	:	105	
Lot no. of calibrator	:	197633	
Exp. date calibrator	:	04/2002	
Recommended at	:	02/28/2000	
R. Pack Calibration			
Reagent pack calibration date	:		
Reagent pack no. for R. pack cal.	:		
Lot no. of calibrator	:		
Exp. date calibrator	:		
Recommended at	:		
Calibration Quality Criteria			
Missing values		-----	
Monotony of curve		-----	
Calibration factor		1.00	
Minimum signal		-----	
Minimum acceptable difference		-----	
Deviation of dup. measurements		-----	
System errors		-----	
Calibrators	1. Signal	2. Signal	Target Value
1 :	2736	2829	0.930 IU/l
2 :	92887	94125	48.30 IU/l

Example of a calibration data report for a quantitative assay

Calibration Status



The calibration status of the test is easily identified on the **CALIBRATION DATA** screen (**UTILITY** folder) by the color of the test button. Three colors are used to distinguish calibration status. They are as follows:

green: Calibration was successful. No further action is necessary.

yellow: Calibration was questionable. Proceed to step 4.

red: Calibration failed. Repeat the calibration for the test.

Follow the instructions below to view the calibration status.

- 1 Touch the  tab to open the **UTILITY** screen.
- 2 Touch the  tab to open the **CALIBRATION DATA** screen.

Stand-by Operator ID: 47 07:40

Calibration Data Utility

TSH 0 191375	6	T4 1 189844	1	T3 0 191210	4	HCGSTAT 0 194538	2	CEA 1 195005	12
AFP 1 192889	3	PSA 1 191898	18	FERR 0 194415	14	B12 0 192905	7	FOL 0 194538	2
DIG 0 190451	8								
									BC Card Scan

3 The color of the test button determines the status.



Follow your laboratory protocol regarding questionable or failed calibration results.

FT4 192882	17
---------------	----

Green: Calibration was successful.

FT4 192882	17
---------------	----

Yellow: Calibration was questionable. You must check the Calibration Data report or view the **CALIBRATION DATA DETAILS** pop-up window to determine which quality criteria were violated. To do so chose a test in the **UTILITY/CALIBRATION** screen and then open the **CALIBRATION DATA DETAILS** pop-up window. You can release this calibration by touching the **Release** button, then **OK**.

Before a calibration is manually released, all sample and control results are calculated using the last valid calibration. After manual release of a calibration, the results of all following pipetted samples are calculated according to this released reagent pack calibration. Controls should be measured again, to check the validity of the manually released calibration. In addition, QC results with the data alarm Previous calibration used should be checked to decide if the patient results obtained at the same time are acceptable.

If the calibration is discarded by touching **Reject**, then **OK**, the last valid calibration is used to calculate subsequent sample results.

17
FT4
192882

Red: Calibration failed. The last valid calibration is used to calculate the sample results. All samples are flagged with Previous calibration used.



Preceding calibrations can only be used if a valid calibration exists in the software. In the case of rejected, questionable calibrations or failed calibrations without a previous valid calibration, the instrument stops sample pipetting. Perform a new calibration.

For additional information on calibration validation, please refer to chapter 6.1, Reagent Calibration in the Reference Guide, chapter 7.3.1, Calibration Data Details or chapter 8.9, Calibration Data Report, both in the Software Guide.

- Review the **CALIBRATION DATA** report for the assay or touch the corresponding test button for the assay to open the **CALIBRATION DATA DETAILS** pop-up window.

Stand-by		Operator ID: 47 07:40	
Calibration Data		Utility	
Test code : HCGSTAT 0 Lot calibration not succesful			
L-Cal date : 05/13/2001 Reagent pack no. : 718 Lot no. calibrator : 192927 Exp. date : 05/2001 Recommended at : 06/12/2001		Calibration Quality Criteria Lot no. calibrator : 194538 Missing values : 1----- Monotony of curve : ----- Calibration factor : 1.0 Minimum signal : ----- Minimum accept. difference : ----- Deviation of dupl. : ----- System errors : -----	
R-Cal date : 05/13/2001 Reagent pack no. : 718 Lot no. calibrator : 192927 Exp. date : 05/2001 Recommended at : 05/20/2001		Cal. 1.signal 2.signal Target 1: 0.000 2613 8.98 2: 720229 712953 4690	
Release		Reject	
OK		Cancel	

- Determine why the calibration was questionable. Refer to the next subsection, Questionable Calibrations, for further information.


- If you wish to accept the calibration, touch **Release**, then touch **OK**.
- If you wish to reject the calibration, touch **Reject**, then touch **OK**.

Questionable Calibrations


If the calibration was questionable (i.e., a yellow test button), you must review the **CALIBRATION DATA** report or the **CALIBRATION DATA DETAILS** pop-up window for the assay and determine the cause. The QC following the questionable calibration was calculated from the last valid calibration and **cannot** be used to validate the questionable curve. In addition, any patient and control results are flagged with the data alarm 26 – Previous calibration used.

For further information on calibration data, refer to section 7.3.1, Calibration Data Details pop-up window or chapter 8.9, Calibration Data Report in the Software Guide.

Release calibration

Press the  button you want to release the calibration. You should then validate the calibration by performing a QC. All results pipetted after the release are calculated by the system using the released calibration.

Reject calibration

If the quality criteria indicates that the calibration can not be used, discard the calibration by pressing the  button. The previous calibration is then valid. A new calibration should be carried out. The results of samples and controls pipetted after the reject will not be flagged.

What's Next?

When calibration validation is complete, proceed to the section 2.6, Routine Sample Measurements – Disk System or section 2.7, Routine Sample Measurement – Rack System.



Calibrations could be performed before daily operations; thus ensuring that all samples can be processed without repetition.

2.6 Routine Sample Measurements – Disk System

Patient test selections can be made at any time during operation.

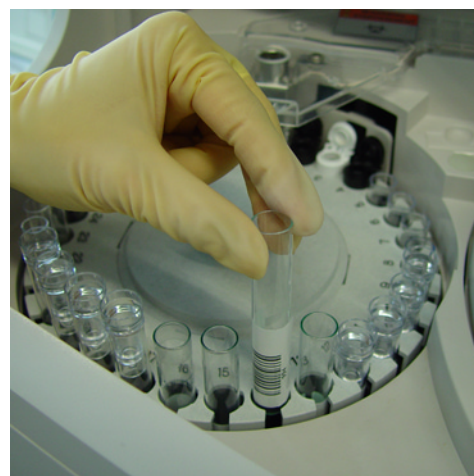
Patient Programming for Interfaced, Bar coded Samples

- 1 Perform sample programming at the host.
- 2 Place the bar coded samples on the sample disk.
Make sure the bar codes are facing out so the bar code reader scans them properly.
- 3 Place a Stop bar code in the next open position on the disk.



If running in the **single** disk mode and you forget the Stop bar code, the disk turns continuously. If calibrators or controls are present, they will be pipetted again.

If running in the **multiple** disk mode and you forget the Stop bar code, the disk stops at position 30.



Load bar coded samples

- 4 Press . As each bar code is scanned the Elecsys queries the host and receives test requests for the sample. The sequence number and position are automatically assigned during this process.

If running in the multiple disk mode, the following screen is displayed after you press .

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
TSH 0 150 6	C M T4 1 180	<div style="background-color: #f0f0f0; padding: 10px; text-align: center;"> Confirmation Current disk no. = 0 Resume this operation? <div style="display: flex; justify-content: space-around; margin-top: 10px;"> Resume Cancel </div> </div>		2	R HCGSTAT 0 100 3
CEA 1 0 12	AFP 1 70			14	FERR 0 94 15
B12 0 25 7	P-B12 25	10	T	DIG 0 88 11	
17	18	Dil Uni 18 16	Cups 100	Tips 360	
Set 1 Set 2 100% 75%	System Water	Liquid Waste	Solid Waste 507	Reagent Scan	

- Verify that the sample disk number reflects the sample disk currently loaded. If the disk number is correct, press **Resume**. If the disk number is incorrect, press **Cancel** and enter the correct disk number on the **STATUS** screen. Subsequently, the analyzer can begin routine operations.




If the host does not answer within 15 seconds, the position is skipped and the disk advances to the next position.

If you are using the batch mode for the analyzer-host-communication, make sure that all requests are loaded from the host to the analyzer.

Patient Programming for Interfaced, Non-Bar coded Samples

- Perform sample programming at the host.
- Download sample IDs, test selections, disk number and position to the analyzer from your host computer. A sequence number is assigned to each sample ID during the download.



Stand-by		Operator ID: 47 07:40		
Inventory	Orders	Results	QC	Utility
Sample ID : 12345	Pre-dil. Off	Sample Control Calibrator		
Sequence No. : 200	Select Control	Dilution Factor		
Disk - Pos. : 1 - 7	Position Search	Sample Cup Normal	Register	
Sample volume : 95 ul				
TSH 0	T4 1	T3 0	HCGSTAT 0	CEA 1
AFP 1	PSA 1	FERR 0	B12 0	P-B12
FOL 0	DIG 0			

- Touch the **Orders** tab to open the **ORDERS** screen.
- Print a work list by pressing .
- Load samples on the sample disk according to the work list.
- Place a Stop bar code in the next open position on the disk.





If running in the **single** disk mode and you forget the Stop bar code, the disk turns continuously. If calibrators or controls are present, they will be pipetted again.

If running in the **multiple** disk mode and you forget the Stop bar code, the disk stops at position 30.

- 7 Press . If running in the single disk mode, the samples will be scanned and pipetted immediately. If running in the multiple disk mode, the following screen is displayed after pressing the  key.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
TSH 0 150 6	C M T4 1 180	<div>Confirmation</div> <div>Current disk no. = 0</div> <div>Resume this operation?</div> <div> <div>Resume</div> <div>Cancel</div> </div>		2	R HCGSTAT 0 100 3
CEA 1 0 12	E AFP 1 70			14	FERR 0 94 15
B12 0 25 7	X P-B12 25	T 10	DIG 0 88 11		
17	18	Dil Uni 18 16	Cups 100	Tips 360	
Set 1 Set 2 100% 75%	System Water	Liquid Waste	Solid Waste 507	Reagent Scan	

Verify that the sample disk number reflects the sample disk currently loaded. If the disk number is correct, press . If the disk number is incorrect, press  and enter the correct disk number on the **STATUS** screen. Subsequently, the analyzer can begin routine operations.


Patient Programming for Non-Interfaced, Bar coded Samples

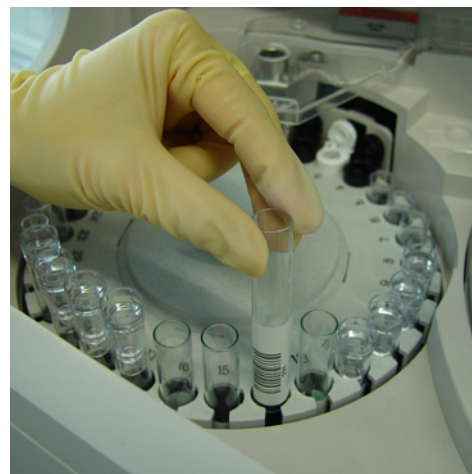
- Place the bar coded samples on the sample disk. Make sure the bar codes are facing out so the bar code reader scans them properly.
- Place a Stop bar code in the next open position on the disk.



If running in the **single** disk mode and you forget the Stop bar code, the disk turns continuously. If calibrators or controls are present, they will be pipetted again.

If running in the **multiple** disk mode and you forget the Stop bar code, the disk stops at position 30.

- Touch the  tab to open the **STATUS** screen.



Load bar coded samples

Stand-by					Operator ID: 47 13:00	
Inventory	Orders	Results	QC	Status	Utility	
Sample Disk Status						
1 Empty	2 Empty	3 Empty	4 Empty	5 Empty	Operator ID	: 47
6 Empty	7 Empty	8 Empty	9 Empty	10 Empty	Disk No.	: 1
11 Empty	12 Empty	13 Empty	14 Empty	15 Empty	Last result at	:
16 Empty	17 Empty	18 Empty	19 Empty	20 Empty	<div>Sample Scan</div> <div>Open Requests</div>	
21 Empty	22 Empty	23 Empty	24 Empty	25 Empty		
26 Empty	27 Empty	28 Empty	29 Empty	30 Empty		

- Touch the

Sample Scan

 button to initiate a sample scan. If running in the **single** disk mode, the samples will be scanned in. Continue with step 6.
- If running in the **multiple** disk mode the following screen is displayed after touching the

Sample Scan

 button.

Stand-by					Operator ID: 47 14:00		
Inventory	Orders	Results	QC	Status	Utility		
Sample Disk Status							
1 Empty	2 Empty	3 Empty	<div>Confirmation</div> <div>Current disk no. = 1</div> <div>Resume Sample Scan?</div> <div>Resume</div> <div>Cancel</div>			or ID	: 47
6 Empty	7 Empty	8 Empty				o.	: 1
11 Empty	12 Empty	13 Empty				esult at	:
16 Empty	17 Empty	18 Empty					
21 Empty	22 Empty	23 Empty	24 Empty	25 Empty	<div>Sample Scan</div> <div>Open Requests</div>		
26 Empty	27 Empty	28 Empty	29 Empty	30 Empty			

The sample disk number displayed, must reflect the sample disk currently loaded. If the disk number is correct, press

Resume

. If the disk number is incorrect, press

Cancel

 and enter the correct disk number on the **STATUS** screen. Subsequently, the scanning-in process begins.

- When the analyzer returns to Stand-by touch the

Orders

 button to open the **ORDERS** screen. The next free sequence number is displayed. Enter the first patient ID.

- 7 Make test selections by touching the test code buttons on the screen. The buttons change to a light blue color when selected.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
Sample ID	: 12345	Pre-dil. Off	Sample Control Calibrator		
Sequence No.	: 200	Select Control	Dilution Factor		
Disk - Pos.	: 1 - 7	Position Search	Sample Cup Normal	Register	
Sample volume	: 95 ul				
TSH 0	T4 1	T3 0	HCGSTAT 0	CEA 1	
AFP 1	PSA 1	FERR 0	B12 0	P-B12	
FOL 0	DIG 0				

- 8 Touch the **Sample Cup Normal** button to toggle to Reduced to utilize reduced dead volume, if necessary. Reduced is only for a Hitachi Standard cup on the sample disk or on top of a tube. Refer to Reference Guide, chapter 2.7, Technical data for a list of dead volumes.

- 9 Touch the **Register** button to register test selections.

- The cursor returns to the **Sample ID** field and shows the next available sample ID.
- The **Sequence No.** increases.
- The next available sample position requiring test selections is displayed.

- 10 Repeat steps 7 - 9 until all samples are programmed.

- 11 Press **Start**. If running in the single disk mode, the samples will be pipetted immediately.

If running in the multiple disk mode, the following screen is displayed after touching the **Start** button.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
TSH 0 150 6	C M T4 1 180	<div>Confirmation</div> <div>Current disk no. = 0</div> <div>Resume this operation?</div> <div>Resume Cancel</div>		R HCGSTAT 0 100 3	
CEA 1 0 12	AFP 1 70				
B12 0 25 7	P-B12 25			T 10	DIG 0 88 11
		Dil Uni 18 16	Cups 100	Tips 360	
Set 1 Set 2 100% 75%	System Water	Liquid Waste	Solid Waste 507	Reagent Scan	

Verify that the sample disk number reflects the sample disk currently loaded. If the disk number is correct, press **Resume**. If the disk number is incorrect, press **Cancel** and enter the correct disk number on the **STATUS** screen. Subsequently, the analyzer can begin routine operations.



Patient Programming for Non-Interfaced, Non-Bar coded Samples

You can only utilize a numeric sample ID when not using sample bar codes.

- 1 Touch the **Orders** tab to open the **ORDERS** screen.

- 2 The cursor defaults to the **Sample ID** field. Type the sample ID of the first sample and press **Enter**.
If no sample ID is entered, the Sample ID field is filled with **@Seq. No.** after pressing the **Register** button.
- 3 The cursor moves to the second **Pos.** field. Type the desired sample disk position. Press **Enter**. Place the sample at the designated position on the disk.
- 4 If running in the multiple disk mode, touch the first **Disk-Pos.** field. Type a disk number (0-9) and press **Enter**.
- 5 Make test selections by touching the test code buttons on the screen. The buttons change to a light blue color when selected.



Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
Sample ID	: 12345	Pre-dil. Off		Sample Control Calibrator	
Sequence No.	: 200	Select Control	Dilution Factor		
Disk - Pos.	: 1 - 7	Position Search	Sample Cup Normal	Register	
Sample volume	: 95 ul				
TSH 0	T4 1	T3 0	HCGSTAT 0	CEA 1	
AFP 1	PSA 1	FERR 0	B12 0	P-B12	
FOL 0	DIG 0				


- 6 Touch the  button to toggle to **Reduced** to utilize reduced dead volume, if necessary. Reduced is only for a Hitachi Standard cup on the sample disk or on top of a tube. Refer to Reference Guide, chapter 2.7, Technical data for a list of dead volumes.
- 7 Touch the  button to register test selections.
 - The cursor returns to the **Sample ID** field.
 - The **Sequence No.** increases.
 - The next available sample position is displayed.
- 8 Repeat steps 2 - 7 until all samples are programmed.
- 9 Place a stop bar code in the next open position on the disk.



If running in the **single** disk mode and you forget the Stop bar code, the disk turns continuously. If calibrators or controls are present, they will be pipetted again.

If running in the **multiple** disk mode and you forget the Stop bar code, the disk stops at position 30.

- 10 Press  to print a work list (optional).
- 11 Press . If running in the **single** disk mode, the sample will be pipetted immediately.

If running in the **multiple** disk mode, the following screen is displayed after touching the  button.

Stand-by				Operator ID: 47 07:40	
Inventory	Orders	Results	QC	Status	Utility
TSH 0 150 6	C M T4 1 180	<div>Confirmation</div> <div>Current disk no. = 0</div> <div>Resume this operation?</div> <div> <div>Resume</div> <div>Cancel</div> </div>		2	R HCGSTAT 0 100 3
CEA 1 0 12	AFP 1 70			14	FERR 0 94 15
B12 0 25 7	P-B12 25			T 10	DIG 0 88 11
		Dil Uni 18 16	Cups 100	Tips 360	
Set 1 Set 2 100% 75%	System Water	Liquid Waste	Solid Waste 507	Reagent Scan	

Verify that the sample disk number reflects the sample disk currently loaded. If the disk number is correct, press **Resume**. If the disk number is incorrect, press **Cancel** and enter the correct disk number on the **STATUS** screen. Subsequently, the analyzer can begin routine operations.

What's Next?


After sample measurements are complete, proceed to section 2.14, Results. If you wish to track samples, add patients during routine operation or process a STAT patient sample, then proceed to one of the following sections:

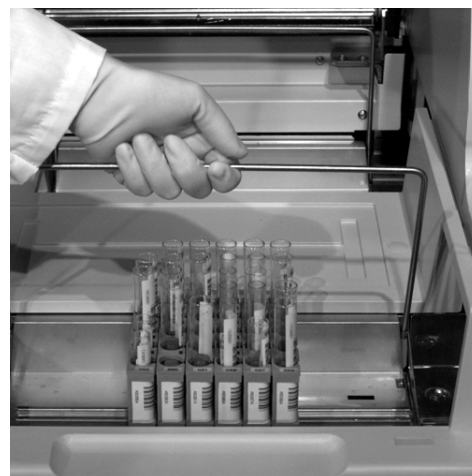
- 2.8 - Sample Tracking – Disk System
- 2.10- Measurement of Additional Routine Samples
- 2.12- STAT Test Selections – Disk System.

2.7 Routine Sample Measurements – Rack System

Patient test selections can be made at any time during operation.

Patient Programming for Interfaced, Bar coded Samples


- 1 Perform sample programming at the host.
- 2 Place the bar coded samples on the sample racks. Make sure the bar codes are visible through the openings on the rack so the bar code reader scans them properly.
- 3 Load the racks on a tray and place the tray on the A-Line (supply). At the same time, verify there is a tray on the C-Line (output buffer). If necessary, place a tray on the C-Line.
- 4 Press  to begin processing samples. As each bar code is scanned the Elecsys 2010 queries the host and receives test requests for the sample. The sequence number, rack ID and rack position are automatically assigned during this process.

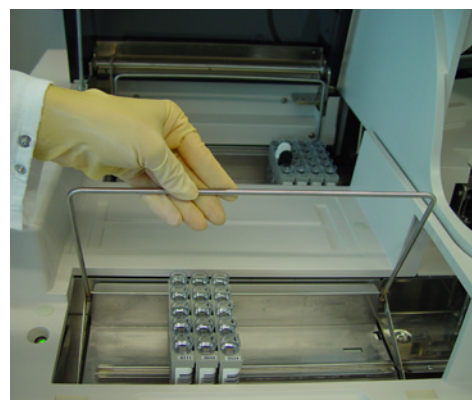


Load bar coded samples on the A-Line

Patient Programming for Interfaced, Non-Bar coded Samples

For REAL-TIME queries:

- 1 Perform sample programming at the host. Make sure to program the rack ID and position number at the host.
- 2 Print a work list at the host.
- 3 Load non-bar coded samples on the sample racks according to the host work list.
- 4 Load the racks on a tray and place the tray on the A-Line (supply). At the same time, verify there is a tray on the C-Line (output buffer). If necessary, place a tray on the C-Line.
- 5 Press  to begin processing samples. As each rack position is encountered, the host is queried to download the sample ID and test selections to the analyzer.



Load samples on the A-Line

Patient Programming for Non-Interfaced, Bar coded Samples

You can only utilize a **numeric** sample ID when not using a host computer. This is because you cannot perform a sample scan (as on the disk system); all sample ID numbers must be entered manually.

- 1 Touch the **Orders** tab to open the **ORDERS** screen.

Stand-by Operator ID: 47 07:40

Inventory Orders Results QC Status Utility

Sample ID :

Sequence No. : 200 Select Control Dilution Factor

Rack ID - Pos. : 1 - Position Search Sample Cup Normal Register

Sample volume : ul

TSH 0 T4 1 T3 0 HCGSTAT 0 CEA 1

AFP 1 PSA 1 FERR 0 B12 0 P-B12

FOL 0 DIG 0

- 2 Touch the **Sample ID** field. Type the sample ID number of the first sample. Press to confirm.
- 3 Make test selections by touching the test code buttons on the screen. The buttons change to a light blue color when selected.

Stand-by Operator ID: 47 07:40

Inventory Orders Results QC Status Utility

Sample ID : 65214578 Pre-dil. Off Sample Control Calibrator

Sequence No. : 200 Select Control Dilution Factor

Rack ID - Pos. : 00005 - 1 Position Search Sample Cup Normal Register

Sample volume : 95 ul

TSH 0 T4 1 T3 0 HCGSTAT 0 CEA 1

AFP 1 PSA 1 FERR 0 B12 0 P-B12

FOL 0 DIG 0

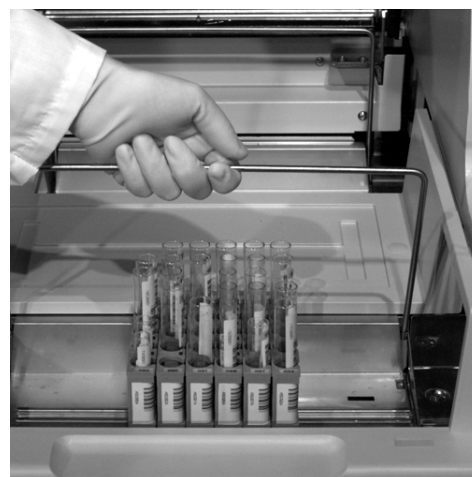
- 4 Touch the **Sample Cup Normal** button to toggle to **Reduced** to utilize reduced dead volume, if necessary. Reduced is only for a Hitachi Standard cup on the sample rack or on top of a tube.
- 5 Touch the **Register** button to register test selections.

- The cursor returns to the **Sample ID** field.
- The **Sequence No.** increases.
- For rack positions 1 - 4, the **Rack Pos.** increases.
For position 5, the **Rack Pos.** returns to 1.
- For rack positions 1 - 5, the **Rack ID** remains unchanged.
After position 5 has been entered, the **Rack ID** clears.



It is not necessary to program a rack ID and position when the sample is bar coded.

- Repeat steps 2 - 5 until all samples are programmed.
- Place the bar coded samples on the sample racks. Make sure the bar codes are visible through the openings on the rack so the bar code reader scans them properly.
- Load the racks on a tray and place the tray on the A-Line (supply). At the same time, verify there is a tray on the C-Line (output buffer). If necessary, place a tray on the C-Line.
- Press to begin processing samples. As each bar code is scanned the rack ID and rack position are automatically assigned during this process.







Load bar coded samples on the A-Line

Patient Programming for Non-Interfaced, Non-Bar coded Samples





You can only utilize a **numeric** sample ID when not using a host computer.

- Touch the tab to open the **ORDERS** screen.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
Sample ID :	<input type="text"/>	Pre-dil. Off	Sample Control Calibrator		
Sequence No. :	200	Select Control	Dilution Factor		
Rack ID - Pos. :	<input type="text"/> - <input type="text"/>	Position Search	Sample Cup Normal	Register	
Sample volume :	ul				
TSH 0	T4 1	T3 0	HCGSTAT 0	CEA 1	
AFP 1	PSA 1	FERR 0	B12 0	P-B12	
FOL 0	DIG 0				

- 2 The cursor defaults to the **Sample ID** field. Type the sample ID of the first sample and press . If no sample ID is entered, the sample ID field is filled with **@Seq. No.** after pressing the  button.
- 3 The cursor moves to the **Rack Pos.** field. Type the rack position and press .
- 4 Touch the **Rack ID** field. Type the rack ID number and press . Place the sample at the designated position on the rack.
- 5 Make test selections by touching the test code buttons on the screen. The buttons change to a light blue color when selected.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
Sample ID	:	65214578	Pre-dil. Off	Sample Control	Calibrator
Sequence No.	:	200	Select Control	Dilution Factor	
Rack ID - Pos.	:	00005 - 1	Position Search	Sample Cup Normal	Register
Sample volume	:	95 ul			
TSH 0	T4 1	T3 0	HCGSTAT 0	CEA 1	
AFP 1	PSA 1	FERR 0	B12 0	P-B12	
FOL 0	DIG 0				

- 6 Touch the  button to toggle to **Reduced** to utilize reduced dead volume, if necessary. Reduced is only for a Hitachi Standard cup on the sample rack or on top of a tube.
- 7 Touch the  button to register test selections.
 - The cursor returns to the **Sample ID** field.
 - The **Sequence No.** increases.
 - For rack positions 1 - 4, the **Rack Pos.** increases.
For position 5, the **Rack Pos.** returns to 1.
 - For rack positions 1 - 5, the **Rack ID** remains unchanged.
After position 5 has been entered, the **Rack ID** clears.
- 8 Repeat steps 2 - 7 until all samples are programmed.
- 9 Press  to print a work list (optional).
- 10 Load the racks on a tray and place the tray on the A-Line (supply). At the same time, verify there is a tray on the C-Line (output buffer). If necessary, place a tray on the C-Line time.
- 11 Press  to begin processing samples.

What's Next?

After sample measurements are complete, proceed to section 2.14, Results. If you wish to track samples, add patients during routine operation or process a STAT patient sample, then proceed to one of the following sections:

- 2.9 - Sample Tracking – Rack System
- 2.10 - Measurement of Additional Routine Samples
- 2.13 - STAT Test Selections – Rack System.

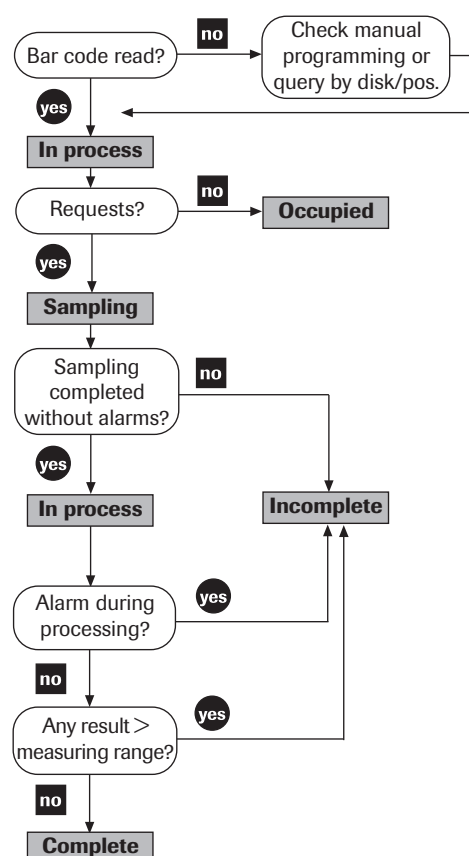
2.8 Sample Tracking – Disk System

Use the **STATUS** screen to monitor the progress through sample processing. The screen displays the status and position number of each sample (max. 30) currently on the disk. The graphic to the right shows an example status flow. Sample disk status conditions are as follows:

- **Compl**, indicates the sample/control is complete and can be removed from the disk (not for calibrators).
- **Empty**, indicates that the position is empty and is ready for a sample.
- **Occup**, indicates that the sample disk position is assigned or empty (i.e., during a sample scan, the bar code reader cannot distinguish between a sample on the disk or an empty position).
- **Smpl**, indicates that the sample is currently being pipetted.
- **Proc**, indicates that the sample, control or calibrator is in process (i.e., all assays have been pipetted), but results are not ready.
- **Incmp**, indicates that there was an error during processing, or the sample has a result greater than the measuring range or calibration fails.
- **Stop**, the stop bar code was scanned.



Sample positions that contain a STAT appear yellow throughout operation, even though their actual status changes.



Sample status flow

To review the status of a sample on the disk system, simply touch the **Status** tab to open the **STATUS** screen. Identify the position number of the sample in question and read the information on the button.

Stand-by
Operator ID: 47 13:00

Inventory Orders Results QC Status Utility

Sample Disk Status

1 Compl	2 Compl	3 Compl	4 Compl	5 Compl	Operator ID : 47 Disk No. : 1 Last result at : 13:46	Sample Scan Open Requests
6 Compl	7 Compl	8 Compl	9 Compl	10 Compl		
11 Compl	12 Incml	13 Compl	14 Compl	15 Compl		
16 Compl	17 Compl	18 Proc	19 Proc	20 Proc		
21 Proc	22 Proc	23 Proc	24 Proc	25 Smpl		
26 Occup	27 Occup	28 Stop	29 Empty	30 Empty		

To obtain more detailed information on the status of a specific position, touch the appropriate button to open the **SAMPLE POSITION STATUS** pop-up window. Refer to the window below.

Stand-by
Operator ID: 47 13:00

Inventory Orders Results QC Status Utility


Sample Position Status



Test	Dil.	Result	Flags	Ready	Type
TSH 0		5.01	49	12:30	Sample
					ID : @123
					Seq. : 123
					Pos. : 1 - 11

Close

2.9 Sample Tracking – Rack System

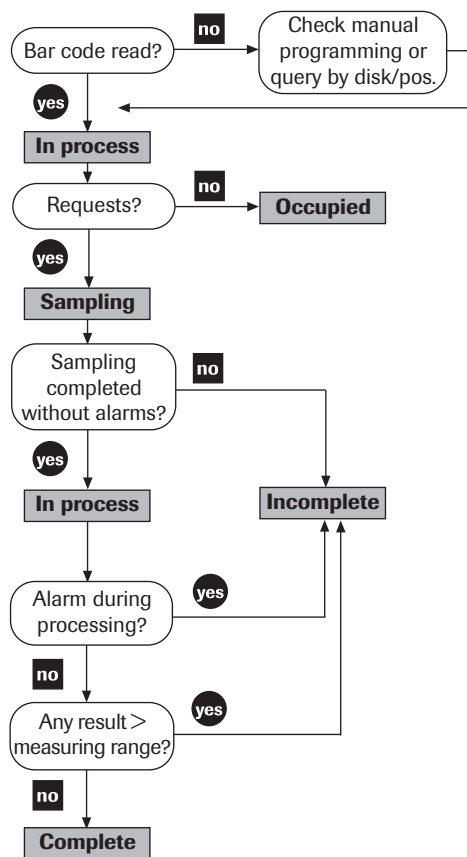
Use the **STATUS** screen to monitor the progress through sample processing. Information about any sample currently in the output buffer or on the C-Line is displayed on one of four status screens.

When you open the **STATUS** screen from any other screen in the software, Tray part 1 (screen 2) is the screen that appears. Press  to view the **BUFFER** screen (screen 1).

Use  and  to move back and forth between the four status screens.

Thirty positions (six rows) are listed on the screen, each row representing a sample rack. To the right of each row is the rack ID number. The upper right corner of each button corresponds to a position on the sample rack. Each position also lists a status. The graphic to the right shows an example status flow. Sample rack status conditions are as follows:

- **Compl**, indicates the sample pipetting is complete and the sample can be removed from the rack on the C-Line.
- **Empty**, indicates that the rack position is empty.
- **Occup**, indicates that the sample rack position is occupied, but not sampled.
- **Smpl**, indicates that the sample is currently being pipetted. This status only appears in row 1, screen 1 (Output Buffer).
- **Proc**, indicates that the sample, control or calibrator is in process (i.e., all assays have been pipetted), but the results are not ready.
- **Incmp**, indicates that there was an error during processing, or the sample has a result greater than the measuring range or calibration fails.



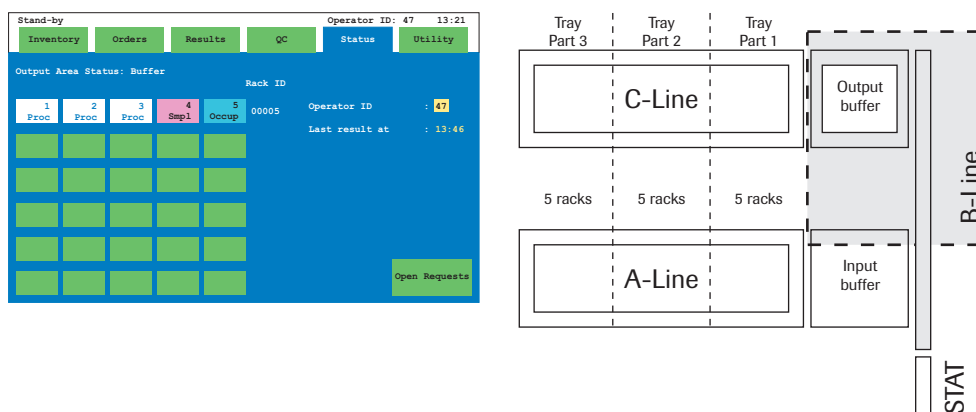
Sample status flow



Sample positions that contain a STAT appear yellow throughout operation, even though their actual status changes.

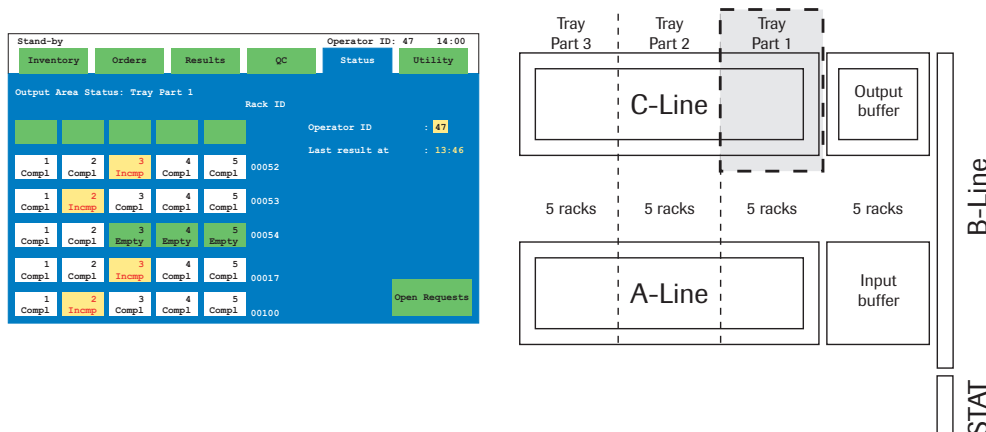
The graphics below show how each of the four screens relates to rack position.

Screen 1 = Output Buffer



The rack currently being processed on the B-Line appears on screen 1, row 1. Usually only the rack being processed appears here. However, if the C-Line tray is full or missing, then the completed racks (max. 5) in the output buffer will also appear on this screen.

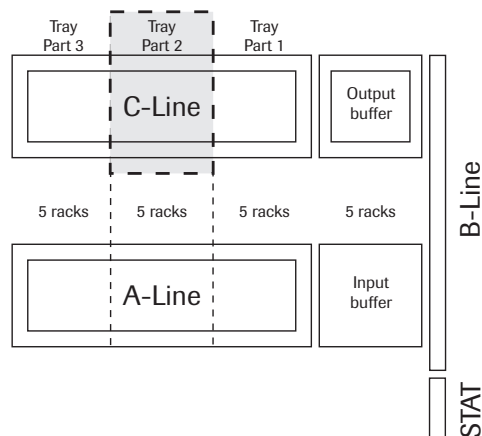
Screen 2 = Tray part 1



Screen 2 holds up to five racks. Row 1 is always empty; it is only utilized in screen 1. The screen updates from top to bottom (i.e., the rack that was processed first appears in row 2 and continues down to row 6. When the next rack is processed, this rack moves from screen 2, row 6 to screen 3, row 2). Therefore, as more racks are processed, they move into tray part 2.

Screen 3 = Tray part 2

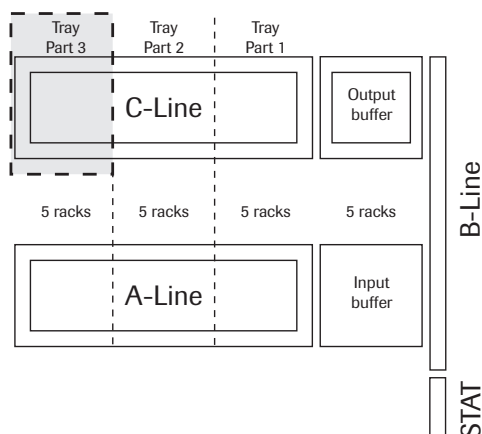
Stand-by					Operator ID: 47 13:21	
Inventory	Orders	Results	QC	Status	Utility	
Output Area Status: Tray Part 2					Rack ID	
1	2	3	4	5	Operator ID	: 47
Compl	Incomp	Compl	Compl	Compl	Last result at	: 13:46
1	2	3	4	5		
Empty	Empty	Empty	Empty	Compl		
1	2	3	4	5		
Compl	Incomp	Compl	Compl	Compl		
1	2	3	4	5		
Compl	Compl	Compl	Compl	Compl		
1	2	3	4	5		
Compl	Compl	Compl	Compl	Compl		
1	2	3	4	5		
Compl	Compl	Compl	Compl	Compl		
1	2	3	4	5		
Empty	Empty	Empty	Empty	Compl		



Screen 3 holds up to six racks. Row 1 shows the last rack of tray part 1. Like screen 2, screen 3 updates from top to bottom. When all five rows are full, screen 3, row 6 moves to screen 4, row 2. Therefore, as more racks are processed, they move into tray part 3.

Screen 4 = Tray part 3


Stand-by					Operator ID: 47 13:21	
Inventory	Orders	Results	QC	Status	Utility	
Output Area Status: Tray Part 3					Rack ID	
1	2	3	4	5	Operator ID	: 47
Empty	Empty	Empty	Empty	Compl	Last result at	: 13:46
1	2	3	4	5		
Compl	Compl	Compl	Empty	Compl		
1	2	3	4	5		
Compl	Compl	Empty	Empty	Empty		
1	2	3	4	5		
Compl	Compl	Compl	Compl	Compl		
1	2	3	4	5		
Compl	Compl	Compl	Compl	Compl		
1	2	3	4	5		
Compl	Compl	Compl	Compl	Compl		
1	2	3	4	5		
Compl	Compl	Compl	Compl	Compl		



Screen 4 holds up to six racks. Row 1 shows the last rack of tray part 2. Like screens 2 and 3, screen 4 updates from top to bottom. When all six rows are full, screen 4, row 6 displays the first rack processed. When the entire output tray of the C-Line is full, the racks then fill the output buffer. The analyzer displays alarm 63-02-02 (C-Line tray is full). When the C-Line and output buffer are completely filled (20 Racks), the analyzer displays alarm 62-02-04 (C-Line and buffer full).



When you replace the output tray from the C-Line, all the information on the status screen disappears..

The **STATUS** screen may not clear immediately after removing the tray from the C-Line. It may not clear until  is next pressed.

To obtain more detailed information on the status of a specific rack ID and position, touch the appropriate button to open the **SAMPLE POSITION STATUS** pop-up window. Refer to the window below.

Stand-by

Operator ID: 47 13:00

Inventory

Orders

Results

QC

Status

Utility

Sample Position Status

Test	Dil.	Result	Flags	Ready	Type
TSH 0		5.2	49	12:30	Sample

Type : Sample
ID : @123
Seq. : 123
Pos. : 0015 - 3

Close

2.10 Measurement of Additional Routine Samples

The procedure for measuring additional routine samples varies, depending on you are running a disk or rack system.



Continuous Loading Using the Single Disk Mode

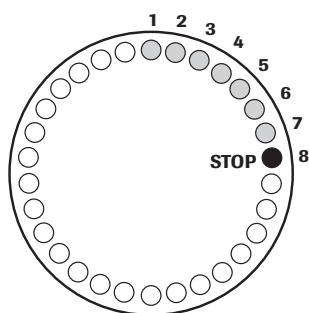
Additional routine samples may be programmed at any time. When the analyzer starts from Stand-by, the system always begins at position 1 on the disk and stops at the position of the Stop bar code.

When the analyzer starts from Sampling Stop, the system remembers the last position where the Stop bar code was, and starts at that position.

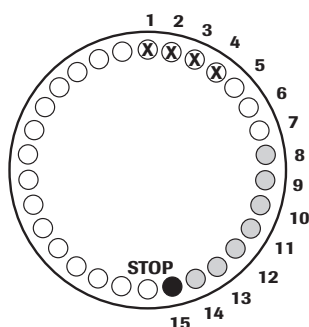


If you forget to place the Stop bar code on the disk, the disk turns continuously. If calibrators or controls are present, they will be pipetted again.

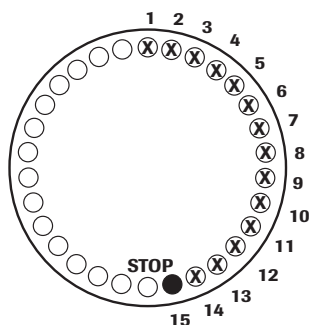
The following example is a graphical representation of continuous loading.



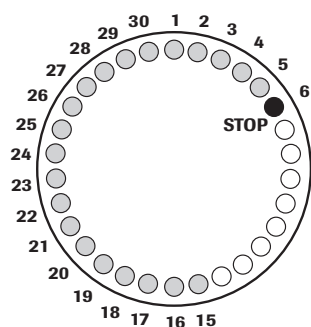
1 Load seven samples on the disk. Place the Stop bar code in position 8.




2 When the sample in position 4 is complete, add seven more samples to the disk. Move the Stop bar code to position 15.



3 All 14 samples have been pipetted. The analyzer goes into Sampling Stop when it reaches the Stop bar code in position 15.



- 4 Add samples starting at position 15 (i.e., the previous position of the Stop bar code). After pressing  the system continues sampling past position 30 until it sees the Stop bar code again (here in position 6).



Continuous Loading Using the Multiple Disk Mode

When the analyzer starts from Stand-by, the system always begins at position 1 on the disk and stops at the position of the Stop bar code.

The analyzer enters the sampling stop mode when it sees the Stop bar code or reaches position 30 on the sample disk.

When the analyzer starts from sampling stop and the system has reached position 30, the analyzer will begin again at position 1. If using multiple disks, you should change the disk and enter the new disk number on the **STATUS** screen prior to pressing start.



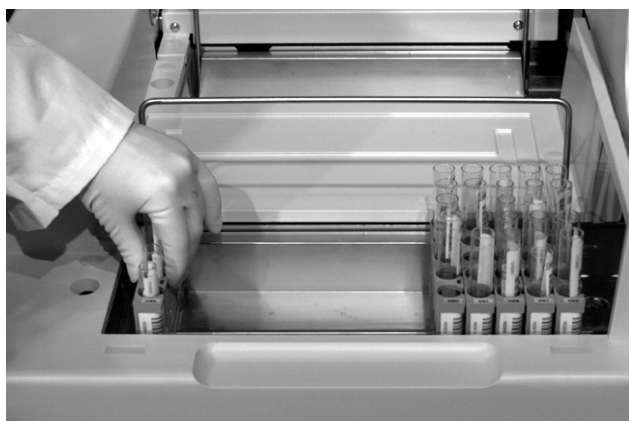
If you forget to place the Stop bar code on the disk, the disk stops at position 30.



Continuous Loading Using the Rack System

There are two ways to continuously load on the rack system.

- Add single racks to the A-Line. Refer to the photograph below.
- Add a loaded tray to the A-Line.

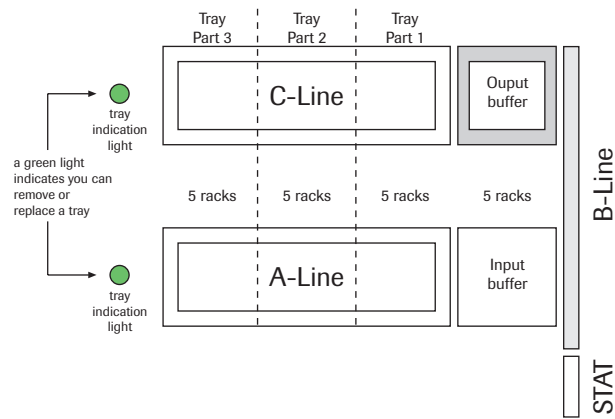


Loading a rack on the A-Line during operation



Caution

You can add single racks to the A-Line only when the tray indication light is green. When the light is out, do not load racks onto the analyzer.



Caution

You can add a tray to the A-Line only when the tray indication light is green. When the light is out, do not load trays onto the analyzer.

2.11 Dilutions

Sample results that exceed the measuring range of the assay must be diluted and measured again. Dilutions can be requested from the **ORDERS** screen and are performed automatically by the analyzer. Refer to the Dilution section of the package insert for recommended dilutions.



The **Dilution Factor** button is only available for assays that are encoded in the reagent bar code as being able to be diluted. Also, the button is only available when a bottle of Diluent Universal is on the analyzer.

The sample result is recalculated based on the selected dilution factor, but the measuring range is not. The resulting diluted sample result is therefore flagged as being outside the measuring range. For additional information on dilutions, please refer to chapter 3, Mechanical Theory in the Reference Guide or chapter 3, Orders in the Software Guide.

Predilution of Samples


You can predilute samples, whereby the analyzer flags the corresponding sample ID (on the reports and on the **RESULTS** screen). The results are NOT calculated using the dilution factor. It is the operator's responsibility to calculate the final results. The following, explains how prediluted samples can be flagged. The procedure is the same for both disk and rack systems; The illustrations utilize screens from a disk system.

- 1 Touch the **Orders** tab to open the **ORDERS** screen.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
Sample ID :	<input type="text"/>	Pre-dil. Off		Sample Control Calibrator	
Sequence No. :	200	Select Control	Dilution Factor		
Disk - Pos. :	1 - <input type="text"/>	Position Search	Sample Cup Normal	Register	
Sample volume :	ul				
TSH 0	T4 1	T3 0	HCGSTAT 0	CEA 1	
AFP 1	PSA 1	FERR 0	B12 0	P-B12	
FOL 0	DIG 0				

- 2 Program your sample as you would normally. Refer to section 2.6, Routine Sample Measurements – Disk System, or section 2.7, Routine Sample Measurement – Rack System for details.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
Sample ID :	<input type="text"/>	Pre-dil. On		Sample Control Calibrator	
Sequence No. :	200	Select Control	Dilution Factor		
Disk - Pos. :	1 - <input type="text"/>	Position Search	Sample Cup Normal	Register	
Sample volume :	ul				
TSH 0	T4 1	T3 0	HCGSTAT 0	CEA 1	
AFP 1	PSA 1	FERR 0	B12 0	P-B12	
FOL 0	DIG 0				


- 3 Touch the **Pre-dil. Off** button to toggle to the **On** choice.
- 4 Touch the **Register** button when complete.
- 5 Press  to begin processing samples. A **P** is shown behind the Sample ID number on the **RESULTS** screen and on the results report. Refer to section 8.5, Results reports in the Software Guide.

Procedure for Automatic Dilution by the Analyzer


Follow the instructions below to dilute a patient sample. The process is the same for both disk and rack systems. The only difference is in the appearance of the Position fields on the **ORDERS** screen. This illustration utilizes screens from a disk system.


- 1 Touch the **Orders** tab to open the **ORDERS** screen.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
Sample ID :	<input type="text"/>	Pre-dil. Off		Sample Control Calibrator	
Sequence No. :	200	Select Control	Dilution Factor		
Disk - Pos. :	1 - <input type="text"/>	Position Search	Sample Cup Normal	Register	
Sample volume :	ul				
TSH 0	T4 1	T3 0	HCGSTAT 0	CEA 1	
AFP 1	PSA 1	FERR 0	B12 0	P-B12	
FOL 0	DIG 0				


- 2 Touch the **Sample ID** field and type the ID (numeric only) of the sample to be diluted. Press .




- 3 The cursor automatically moves to the second **Pos.** field. Type the sample disk position. Press  to confirm.


The cursor automatically moves to the **Rack Pos.** field. Type the position number and press  to confirm.

- 4 Proceed to step 5.

Touch the **Rack ID** field. Type the rack ID and press  to confirm.

- 5 Touch the test button of the assay that requires dilution. The test button color changes to light blue. At the same time, the text on the  button turns black, indicating that the **DILUTION FACTOR** pop-up window is available.

Stand-by			Operator ID: 47 07:40		
Inventory	Orders	Results	QC	Status	Utility
Sample ID : 12345	Sequence No. : 200	Select Control	Pre-dil. Off	Dilution Factor	Sample Control Calibrator
Disk - Pos. : 1 - 7	Sample volume : 15 ul	Position Search	Sample Cup Normal	Register	
TSH 0	T4 1	T3 0	HCGSTAT 0	CEA 1	
AFP 1	PSA 1	FERR 0	B12 0	P-B12	
FOL 0	DIG 0				

- 6 Touch the  button to open the **DILUTION FACTOR** pop-up window.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
Sample ID	: 12345	Pre-dil. Off	Sample Control Calibrator		
Sequence No.	: 200	Select	Dilution		
Disk - Pos.		Dilution Factor			Register
Sample vol		HCGSTAT			
TSH 0		2	5	No dilution	CEA 1
AFP 1		10	20		P-B12
FOL 0		50	100	Close	

- 7 Touch the button displaying the recommended dilution factor. The button color changes to light blue. Refer to the package insert for the recommended dilutions.
- 8 Touch the Close button to close the **DILUTION FACTOR** pop-up window. The dilution factor is shown in the appropriate test button and printed in the reports.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
Sample ID	: 12345	Pre-dil. Off	Sample Control Calibrator		
Sequence No.	: 200	Select Control	Dilution Factor		
Disk - Pos.	: 1 - 7	Position Search	Sample Cup Normal	Register	
Sample volume	: 15 ul				
TSH 0	T4 1	T3 0	HCGSTAT 0 Dil.= 20	CEA 1	
AFP 1	PSA 1	FERR 0	B12 0	P-B12	
FOL 0	DIG 0				

- 9 Touch the Register button to register the dilution test selection.
- 10 Press Start to initiate operation. The sample is automatically diluted by the 2010 analyzer. When calculating the final sample concentration, the software calculates the result based on the selected dilution factor.

2.12 STAT Test Selections – Disk System

STAT patient test selections can be made when the instrument is in Operation, S. Stop or Stand-by.



During STAT processing, the current sample finishes pipetting. The STAT samples are pipetted next. When the STAT sampling is complete, the analyzer proceeds to the next sample (i.e., the sample directly after where it had previously stopped) and resumes pipetting routine samples.

STAT Patient Programming for Interfaced, Bar coded or Non-Bar coded Samples








In the STAT mode, when the **ORDERS** screen is accessed, the software suggests an available disk position. You can override the position suggested by the system.



Test selections must be made at the host system prior to sample query from the analyzer.



- 1 Press .
- 2 Touch the  tab to open the **ORDERS** screen.

Stand-by		STAT		Operator ID: 47 07:40	
Inventory	Orders	Results	QC	Status	Utility
STAT					
STAT Sample ID : <input type="text"/>		Pre-dil. Off		Sample Control Calibrator	
Sequence No. : 201		Select Control		Dilution Factor	
Disk - Pos. : 1 - 6		Position Search		Sample Cup Normal	
Sample volume : u1				Register	
TSH 0	T4 1	T3 0	HCGSTAT 0	CEA 1	
AFP 1	PSA 1	FERR 0	B12 0	P-B12	
FOL 0	DIG 0				

- 3 If using bar coded samples, proceed with step 5.
If using non-bar coded samples, load the STAT sample in the suggested disk position or a different open position on the sample disk. If you change the disk position you must press  and  before proceeding.
- 4 Touch the appropriate test buttons to select assays.
- 5 Touch the  button to utilize reduced dead volume, if necessary.
- 6 Touch the  button to register test selections and advance to the next sample.
- 7 Repeat steps 3 - 6 for all remaining STAT samples.
- 8 Press . If running in the multiple disk mode, touch  after verifying the sample disk number.
- 9 Press  to exit the STAT mode.

STAT Patient Programming for Non-Interfaced, Bar coded or Non-Bar coded Samples

In the STAT mode, when the **ORDERS** screen is opened an available disk position is suggested by the software. You can override the position suggested by the system.



- 1 Press .
- 2 Touch the  tab to open the **ORDERS** screen.

Stand-by		STAT		Operator ID: 47 07:40	
Inventory	Orders	Results	QC	Status	Utility
STAT					
STAT Sample ID : <input type="text"/>		Pre-dil. Off		Sample Control Calibrator	
Sequence No. : 201		Select Control		Dilution Factor	
Disk - Pos. : 1 - 6		Position Search		Sample Cup Normal	
Sample volume : ul				Register	
TSH 0	T4 1	T3 0	HCGSTAT 0	CEA 1	
AFP 1	PSA 1	FERR 0	B12 0	P-B12	
FOL 0	DIG 0				






- 3 If using bar coded samples, proceed to step 5.

If using non-bar coded samples:

Touch the **STAT Sample ID** field, type the sample ID (numeric only) of the sample and press  to confirm.

- 4 Load the STAT sample in the selected disk position on the sample disk, press  and then touch the  button.
- 5 Touch the appropriate test buttons to select assays.

Stand-by		STAT		Operator ID: 47 07:40	
Inventory	Orders	Results	QC	Status	Utility
STAT					
STAT Sample ID : 67890		Pre-dil. Off		Sample Control Calibrator	
Sequence No. : 201		Select Control	Dilution Factor		
Disk - Pos. : 1 - 6		Position Search	Sample Cup Normal		Register
Sample volume : 95 ul					
TSH 0	T4 1	T3 0	HCGSTAT 0	CEA 1	
AFP 1	PSA 1	FERR 0	B12 0	P-B12	
FOL 0	DIG 0				

- 6 Touch the  button to utilize reduced dead volume, if necessary.
- 7 Touch the  button to register test selections and advance to the next sample.
- 8 Repeat steps 3 - 7 for all remaining STAT samples.
- 9 Press . If running in the multiple disk mode, touch  after verifying the sample disk number.
- 10 Press  to exit the STAT mode.

2.13 STAT Test Selections – Rack System


STAT patient test selections can be made when the instrument is in Operation, R. Stop, Stand-by or Stop. During STAT processing, the current sample rack finishes pipetting. The samples in the STAT rack are pipetted next. When the STAT sampling is complete, the analyzer proceeds to the next rack on the A-Line and resumes pipetting routine samples.

STAT Patient Programming for Interfaced, Bar coded Samples

- 1 Perform sample programming at the host.
- 2 Place the bar coded STAT samples on a sample rack. Make sure the bar codes are visible through the openings on the rack so the bar code reader scans them properly.
- 3 Load the rack in the STAT position.




Refer to the label on the STAT position to ensure correct orientation of the rack.

- 4 Press  to begin processing samples. As each bar code is scanned the Elecsys 2010 queries the host and receives test selections for the sample. The sequence number, rack ID and rack position are automatically assigned during this process.



Load bar coded samples at STAT position



If multiple STAT racks are necessary, you must press  each time a STAT rack is loaded in the STAT position.

STAT Patient Programming for Non-Interfaced, Bar coded and Non-Bar coded Samples

You can only use a **numeric** sample ID when not using a host computer.

- 1 Load the sample in the rack.

If using bar coded samples:

Make sure the bar codes are visible through the openings on the rack so the bar code reader scans them properly.

- Touch the **Orders** tab to open the **ORDERS** screen.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
Sample ID :	<input type="text"/>	Pre-dil. Off	Sample Control Calibrator		
Sequence No. :	200	Select Control	Dilution Factor		
Rack ID - Pos. :	<input type="text"/> - <input type="text"/>	Position Search	Sample Cup Normal	Register	
Sample volume :	ul				
TSH 0	T4 1	T3 0	HCGSTAT 0	CEA 1	
AFP 1	PSA 1	FERR 0	B12 0	P-B12	
FOL 0	DIG 0				

- The cursor defaults to the **Sample ID** field. Type the sample ID number of the first sample. Press to confirm.

If using bar coded samples:

proceed to step 6.

- If using non bar coded samples:

Touch the **Rack ID** field. Type the appropriate rack ID number and press to confirm. Place the sample at the designated position on the rack.

- The cursor moves to the **Rack Pos.** field. Type the rack position (1-5) and press to confirm.


- Make test selections by touching the test code buttons on the screen. The buttons change to a light blue color when selected.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
Sample ID :	65214578	Pre-dil. Off	Sample Control Calibrator		
Sequence No. :	200	Select Control	Dilution Factor		
Rack ID - Pos. :	00005 - 1	Position Search	Sample Cup Normal	Register	
Sample volume :	95 ul				
TSH 0	T4 1	T3 0	HCGSTAT 0	CEA 1	
AFP 1	PSA 1	FERR 0	B12 0	P-B12	
FOL 0	DIG 0				


- 7 Touch the **Sample Cup** button to toggle to **Reduced** to utilize reduced dead volume, if necessary. Reduced is only for a cup on the sample rack or on top of a tube.
- 8 Touch **Register** to register test selections.
 - The cursor returns to the **Sample ID** field.
 - The **Sequence No.** increases.
- 9 Repeat steps 3 - 8 until all STAT samples are programmed.
- 10 Load the rack in the STAT position.



Refer to the label on the STAT position to ensure correct orientation of the rack.

- 11 Press  to begin processing samples.



If multiple STAT racks are necessary, you must press  each time a STAT rack is loaded in the STAT position.




Load bar coded samples at STAT position

STAT Patient Programming for Interfaced, Non-Bar coded Samples


- 1 Perform sample programming at the host.
- 2 Print a work list at the host.
- 3 Load the STAT non-bar coded sample on the sample rack according to the host work list.
- 4 Load the rack in the STAT position.



Refer to the label on the STAT position to ensure correct orientation of the rack.

- 5 Press  to begin processing samples. As each STAT position is encountered, the host is queried to download the sample ID and test selections to the analyzer.



If multiple STAT racks are necessary, you must press the  key each time a STAT rack is loaded in the STAT position.





Load non-bar coded samples at STAT position

2.14 Results

You can evaluate control and patient results on printed reports or on the **RESULTS** screen. All samples can be viewed, printed or uploaded from the **RESULTS** screen. The database hold up to 600 results, depending upon the number of orders in the system. Once the figure of 600 documents is reached, the oldest result will be deleted automatically. You can also manually delete documented samples from the database to free additional space.

Viewing Patient Results

As soon as results are printed, uploaded or printed/uploaded, they are considered to be documented (the documentation mode is defined in **UTILITY/DOCUMENTATION SETUP**). After documentation, the word Documented appears to the right of the sequence number. Partial sample results can be viewed from this screen as soon they are made available by the system.


You can search for information on a patient by touching the **Sequence No.** field and pressing  or  until the appropriate patient sample is found.

You can also search for a patient by touching the **Sample ID** field and typing the sample ID (numeric only).

Refer to the example for the disk system below. The only difference in appearance between disk and rack systems is in the Position fields.

Stand-by		Operator ID: 47		15:00	
Inventory	Orders	Results	QC	Status	Utility
Sample ID	:	23456		Filter Off	Document
Sequence No.	:	1			
Disk - Pos.	:	1 - 7		Samples : 101	Delete Doc. Samples
14:46 HCGSTAT 0 189					

Filtering Patient Results

Using this function you can filter the type of samples you want to view, document or print. Touch the  button to open the **FILTER SELECTION** pop-up window (as seen below). Here you can activate the filtering feature and select the filter mix you wish to see. The default setting for **Filtering** is **Off** and the choice is **All**. The total number of samples filtered according to the choices made is displayed in the **Samples** field below the button. Refer to the red circle above.

Stand-by		Operator ID: 47 15:00	
Inventory	Orders	Results	QC
Sample ID : 23456 P		Filter Off	Document
Sequence No. : 1			
Disk	Filter Selection		
	Routine/STAT	Routine	STAT
	Type	Samples	Controls
	Document	Non Doc.	Doc.
	Filtering Off	OK	Cancel

Blocking Patient Results

You can block or release any patient results prior to documenting, but only if automatic options (printing and/or uploading) are set to OFF in the **DOCUMENTATION** pop-up window (**UTILITY** folder). Touch the button of a specific test to view the details of that test such as expected values, any data flags and release status. Refer to the example below.

Stand-by		Operator ID: 47 15:00	
Inventory	Orders	Results	QC
Sample ID : 76354446		Document	
Sequence No. : 154 Do			
Disk - Pos. : 1 - 7			
14:16 TNTSTAT 7.23 49	14:25 TSH 0 2.10	TSH 0 Sampling time: 14:07 Ready time : 14:25 Result : 2.10 uIU/ml Lower limit : 0.27 Upper limit : 4.2 Note : Dil. factor : Flags : Status : Released Signal :	
		Block	Close

A result can be blocked by touching the **Block** button. These results are marked Blocked on reports (not in the condensed printout configuration) and are flagged with a **B** in the data stream that is sent to the host computer when the sample is uploaded.

Document Patient Results by Printing

The **DOCUMENTATION SETUP** screen (**UTILITY** folder) allows you to select the desired document option. The selected button is colored light blue. Results can be repeatedly printed out from the **RESULTS** screen.

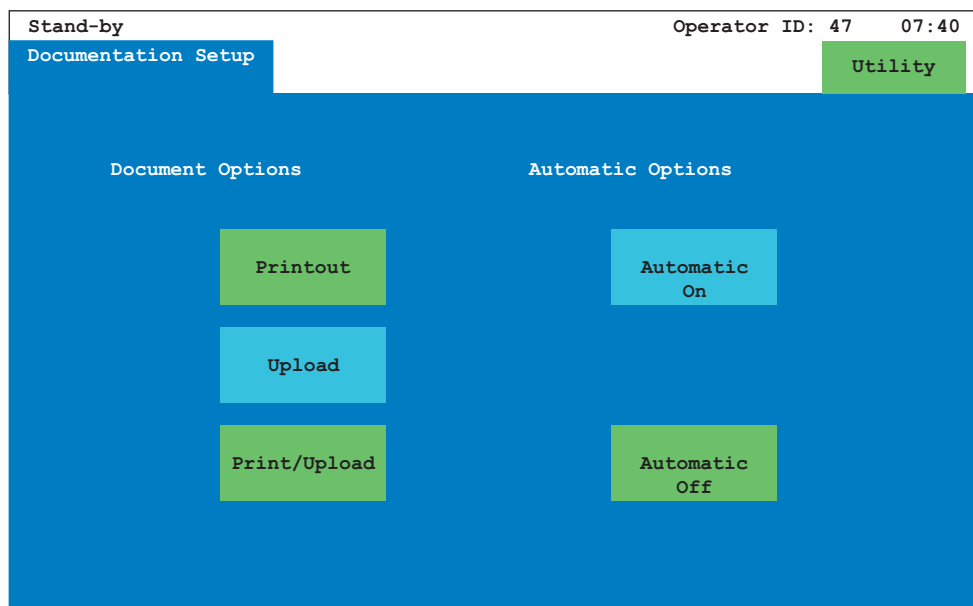
The following automatic options are available, depending upon the chosen setting.

Automatic On Results print automatically (documented), as soon as all results of a sample are available.

Automatic Off No results are printed (documented).

Document Patient Results by Uploading

The **DOCUMENTATION SETUP** screen (**UTILITY** folder) allows you to select the desired document option. Results can be uploaded to the host more than one time, if necessary. The selected button is colored light blue. If a problem occurs with your host interface, change your document option to **Printout**. Results can be uploaded at a later time, if necessary, provided they have not been overwritten (the database can hold up to 600 results). The following automatic options are available, depending upon the chosen setting.



Automatic On Results upload automatically to the host when all results of a sample are available.

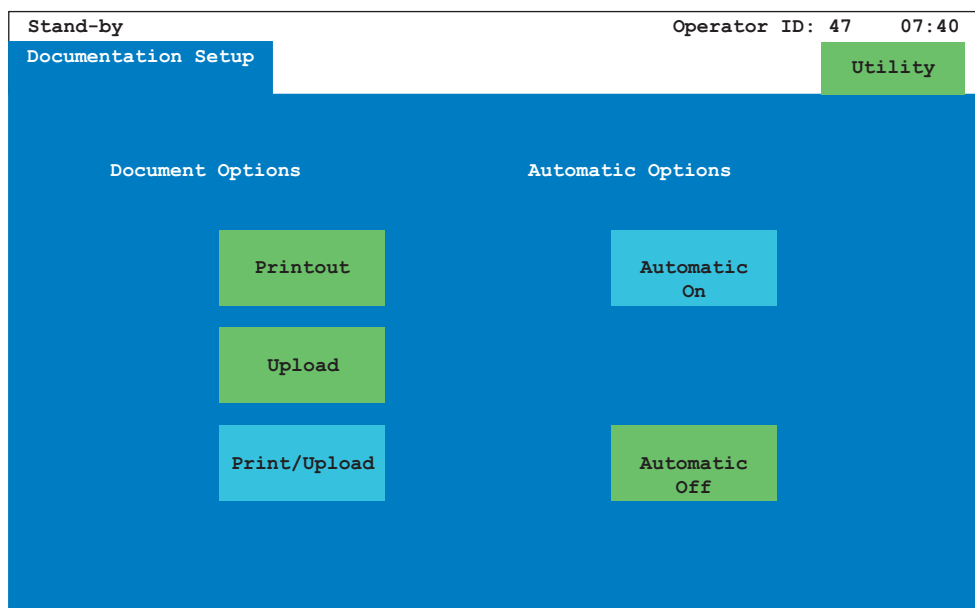
Automatic Off Automatic results upload is disabled.



If the host communication is set to **OFF** (**INTERFACE SETUP** pop-up window, **UTILITY** folder), an alarm is displayed. You must also change the **Document Options** to **Printout** in the **DOCUMENTATION SETUP** screen.

Document Patient Results by Printing/Uploading

The **DOCUMENTATION SETUP** screen (**UTILITY** folder) allows you to select the desired document option. Results can be printed out or uploaded to the host more than one time, if necessary. The selected button is colored light blue. If a problem occurs with your host interface, change your document option to **Printout**. Results can be uploaded at a later time, if necessary, provided they have not been overwritten.



The following automatic options are available, depending upon the chosen setting.

Automatic On Results print out and upload automatically to the host when all results of a sample are available.

Automatic Off No results are printed or uploaded.



If either the print out or upload function is activated by itself, then no results will be "documented" and take up memory space. They must be correctly documented (Filter button, in the **RESULTS** screen).

If the host communication is set to **OFF** (**INTERFACE SETUP** pop-up window, **UTILITY** folder), an alarm is displayed. You must also change the **Document Options** to **Printout** in the **DOCUMENTATION SETUP** screen.

Saving Patient Sample Results

All sample results are saved automatically by the software into the instrument's memory, as well as on the data disk. The capacity is 600 test records (i.e., orders, tests in process and documented test results). After that number is reached, the oldest result will be deleted automatically.

2.15 Post-Operation Data Management



Review Results

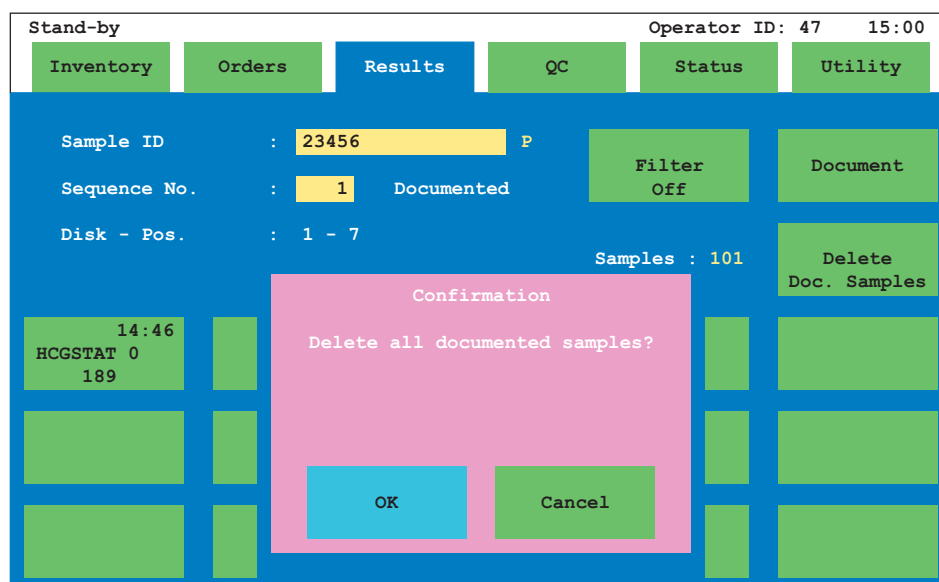
You should review the results as they become available using the printout or on the **RESULTS** screen. Questionable results or those with an incomplete status should be repeated and/or blocked, as necessary, in the **RESULT DETAILS** pop-up window. Remember, your automatic options must be set to **OFF** in the **DOCUMENTATION SETUP** screen (**UTILITY** folder) to be able to block results.

Delete Documented Samples

Samples are considered documented once they are printed out and/or uploaded to the host.

Documented samples should be deleted from the database to free up additional space in the database. Filter settings have no effect on this function.

- 1 Touch the  tab to open the **RESULTS** screen.
- 2 Touch the  button to open the **CONFIRMATION** pop-up window.



- 3 Touch the  button. All documented samples will be deleted from the database.

2.16 Daily Maintenance

Daily maintenance is minimal on the Elecsys 2010 analyzer. At some point during the day clean the S/R probe.

**Caution**

DO NOT clean the mixer. Cleaning the mixer may alter the adjustments and cause movement errors.

Clean the S/R Probe

Operator time:	Approximately 1 minute
Analyzer time:	None
Precautions:	The operation switch must be OFF
Materials required:	Gauze squares Distilled or deionized water

- 1 Power off the operation switch at the front of the analyzer.

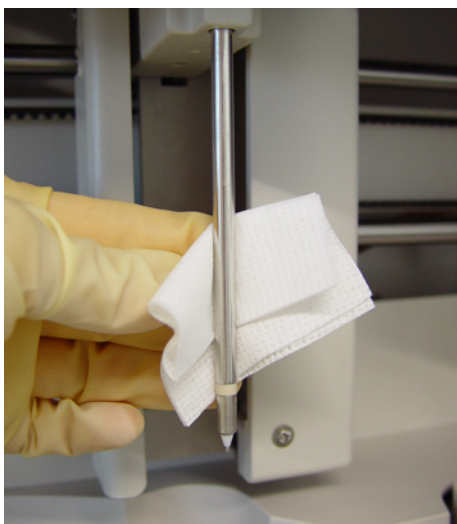
**Caution**

Power must be off to move analyzer components. If power is on, the motors are engaged and attempted movement may damage these components.

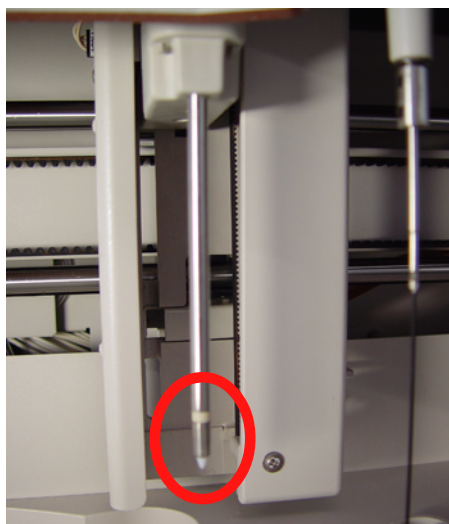
- 2 Move the S/R probe to an area where you can readily access it.
- 3 Wipe the outer surfaces of the S/R probe and probe tip with a gauze square soaked in distilled or deionized water.

**Caution**

Do not bend the probe during cleaning! Be careful to not damage the lower end of the S/R probe.





Wipe S/R probe



S/R probe tip

- 4 Power ON the analyzer.

Finalization Maintenance

Finalization is the analyzer status that occurs between the time when the analyzer stops pipetting samples (S. Stop or R. Stop) and Stand-by. Pressing the  key when the analyzer status is S. Stop or R. Stop bypasses finalization and puts the analyzer directly into Stand-by. If the Elecsys 2010 analyzer does not automatically enter finalization status during the course of the day (i.e., continuously loading the analyzer or pressing ) , you must initiate finalization maintenance.





Finalization allows the analyzer to stand unused for several hours (e.g., overnight). The measuring cell is filled with ProCell, the sipper probe is cleaned with system water and the pipettor rinse station will be primed with system water every 30 minutes.

Operator time: Approximately 30 seconds

Analyzer time: Approximately 5 minutes

Precautions: None

Materials required: None

- 1 Open lids on ProCell/CleanCell.
- 2 Touch the  folder tab.
- 3 Touch the  button.
- 4 Touch the  button to open the **FINALIZATION MAINTENANCE** pop-up window.
- 5 Touch .

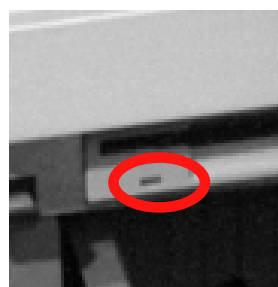
Analyzer Power OFF Recommendations

Power OFF the analyzer using the operation switch. Leave the circuit breaker ON. Power to the circuit breaker keeps the reagent disk temperature-controlled.

The operation switch located on the front panel can be switched off during operation. The screen turns black when all samples are processed, when the automatic finalization procedure has been completed and when all motors have been de-energized.



Make sure that the disk drive is not active when you power off the analyzer. The system is updating files on the data disk when the light is active.



In addition, close the lids on the ProCell/CleanCell bottles to prevent evaporation.

If the analyzer is to be powered OFF at the circuit breaker, move reagent packs to the refrigerator as temperature control to the reagent disk will be off. Make sure that the reagent pack lids are tightly closed.

If the analyzer is to be powered OFF for longer than 7 days, please refer to chapter 4, Maintenance in the User's Guide, for further details.



Close ProCell/CleanCell bottles

3. How to...

3.1 How to Manually Select Calibration for a Reagent Pack

Manual calibration selection of reagent packs allows the calibration of multiple reagent packs.


Single Assay/Single Lot; Multiple Reagent Packs

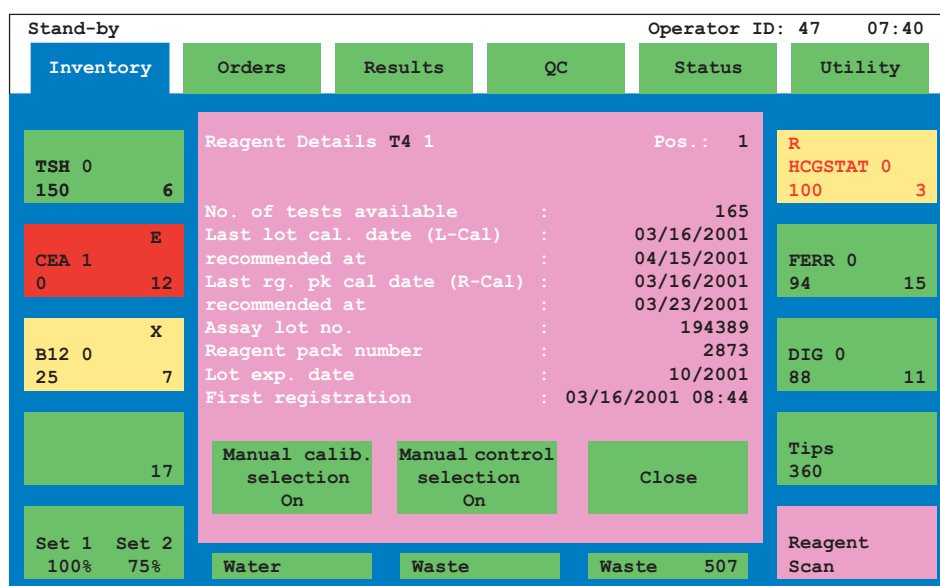
The following criteria are given:



- Single assay
- Several reagent packs with existing L-Cal on the analyzer.

The analyzer always automatically calibrates the reagent pack with the greatest amount of content. If several reagent packs are loaded on the disk with the same amount of content, the analyzer prioritizes the reagent pack in the lowest disk position.


To calibrate a further reagent pack for the same test, touch the appropriate button for the reagent pack to open the **REAGENT DETAILS** pop-up window.

- 1 Touch  to initiate a reagent scan.
- 2 Touch the test button of the reagent pack which should be calibrated. The **REAGENT DETAILS** window for the selected test opens.



- 3 Touch the  button and toggle the choice to **On**. The button turns light blue when selected.
- 4 Touch  to exit the pop-up window. The color of the test button changes to yellow and also indicates a black **C**.
- 5 Repeat steps 1 - 4 for each reagent pack that requires calibration.
- 6 Load the CalSet vials in the same order as shown below onto the sample carrier.



- 7 Press the  key to initiate calibration.

3.2 How to Manually Select a Calibrator

If you want to measure calibrators in containers other than the CalSet vials, then the calibrators must be ordered manually. If a bar code label is damaged or missing, then the calibrator must be ordered manually.

- 1 Perform a bar code scan in the **UTILITY/CALIBRATION DATA** screen.
- 2 Touch the **Orders** tab to access the **ORDERS** screen.


The screenshot shows the 'ORDERS' screen with a top navigation bar containing 'Stand-by', 'Inventory', 'Orders' (selected), 'Results', 'QC', 'Status', and 'Utility'. The top right corner displays 'Operator ID: 47' and '07:40'. The main area has a blue background with white text. At the top, there are input fields for 'Sample ID', 'Sequence No.' (set to 200), 'Disk - Pos.' (set to 1), and 'Sample volume' (set to ul). To the right of these fields are buttons for 'Pre-dil. Off', 'Sample Control Calibrator', 'Select Control', 'Dilution Factor', 'Position Search', 'Sample Cup Normal', and 'Register'. Below these are five rows of assay buttons: TSH 0, T4 1, T3 0, HCGSTAT 0, CEA 1; AFP 1, PSA 1, FERR 0, B12 0, P-B12; and FOL 0, DIG 0, followed by empty slots.


- 3 Touch the **Sample Control Calibrator** button to toggle to the **Calibrator** choice. The **Sample ID** field changes to **Calibrator ID**.
- 4 Touch the test button for the assay to be calibrated. This opens the **SELECT CALIBRATOR** pop-up window.
- 5 Touch the appropriate calibrator test button. The button turns light blue when selected.

The screenshot shows the 'SELECT CALIBRATOR' pop-up window overlaid on the 'ORDERS' screen. The pop-up has a pink background. At the top, it shows 'Calibrator ID' (empty), 'Sequence No.' (set to 200), 'Disk - Pos.' (set to 6), and 'Sample volume'. Below this, there are two columns of buttons: 'Cal 1 194414' and 'Cal 2 194414'. At the bottom, there are 'OK' and 'Cancel' buttons. The background screen shows the 'ORDERS' screen with the 'Sample Control Calibrator' button highlighted in light blue.

- 6 Touch the  button to confirm your selection.




- 7 Touch the second **Pos.** field. Type the desired sample disk position. Press . Place the calibrator at the designated position on the disk.

- 8 If running in the multiple disk mode, touch the first **Disk - Pos.** field. Type a disk number (0-9) and press .




- 7 Touch the **Rack ID** field. Type the appropriate rack ID. Press .


- 8 The cursor moves to the **Rack Pos.** field. Type a rack position number (0-5) and press . Place the calibrator at the designated position on the rack.

Stand-by		Operator ID: 47 07:40			
Inventory	Orders	Results	QC	Status	Utility
Calibrator ID : Cal 1		Pre-dil. Off		Sample Control	
Sequence No. : 200		Select Control	Dilution Factor		Calibrator
Disk - Pos. : 1 - 10		Position Search	Sample Cup Normal		Register
Sample volume : ul					
TSH 0	T4 1	T3 0	HCGSTAT 0	CEA 1	
AFP 1	PSA 1	FERR 0	B12 0	P-B12	
FOL 0	DIG 0				



- 9 Touch the  button to register the calibrator
- The cursor returns to the **Calibrator ID** field.
 - The **Sequence No.** increases.
 - The next available sample position is displayed.





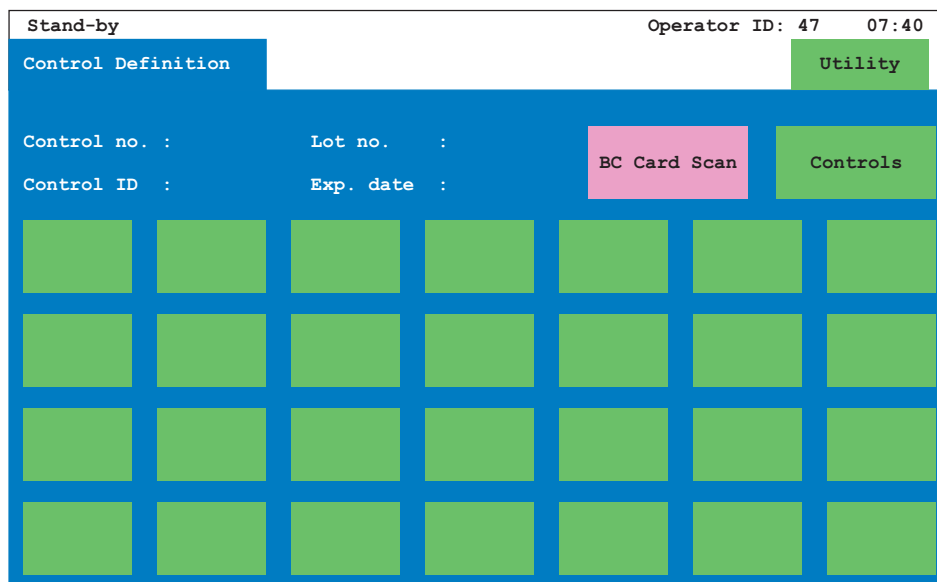
- 9 Touch the  button to register the calibrator
- The cursor returns to the **Calibrator ID** field.
 - The **Sequence No.** increases.
 - For rack positions 1 - 4, the **Rack Pos.** increases. For position 5, the **Rack Pos.** returns to 1.
 - For rack positions 1 - 5, the Rack ID remains unchanged. After position 5 has been entered, the **Rack ID** clears.



- 10 Repeat steps 3 - 9 for any additional calibrators.

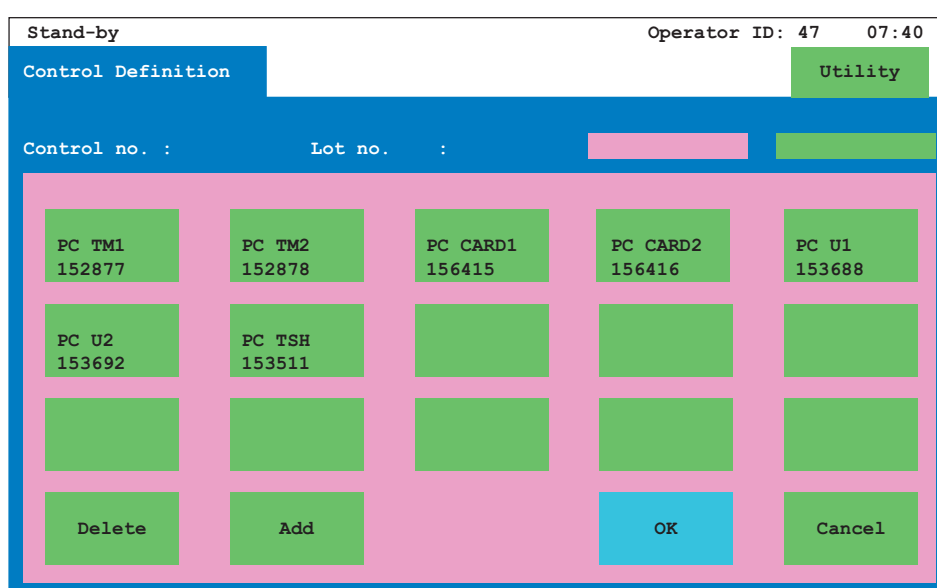
3.3 How to Define Roche (Bar coded) Controls

Before you can run controls or make manual control selections, you must define your controls in the **CONTROL DEFINITION** screen.


- 1 Touch the  tab to open the **UTILITY** screen.
- 2 Touch the  button to open the **CONTROL DEFINITION 1** screen.

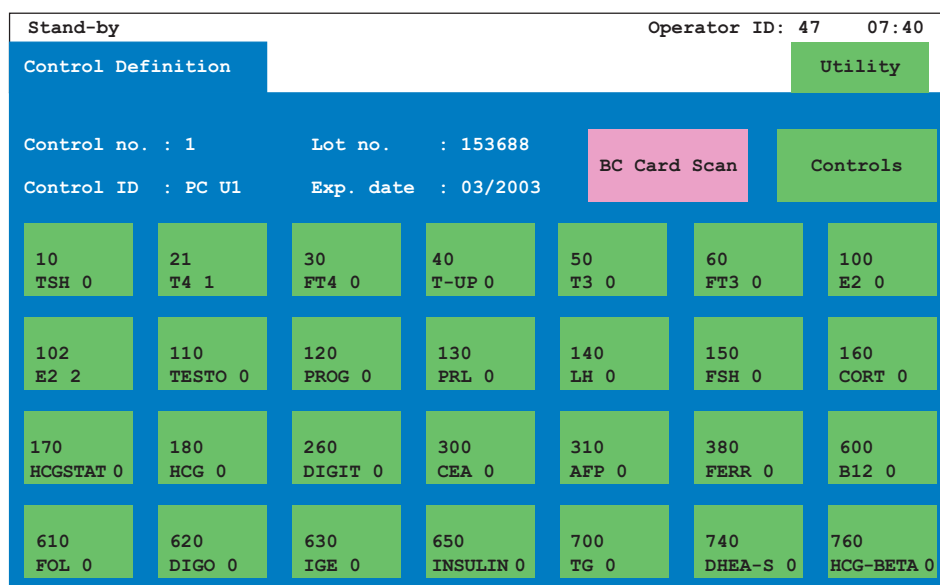


- 3 Insert the control bar code card into the card reading station. The bar code must face toward the back of the analyzer. Push the card as far down as it will go into the station.
- 4 Touch the  button to initiate the bar code card scan. The bar code reader beeps when the scanning in has been successfully completed. From the Stand-by mode repeat steps 1 to 4 for each control card.
- 5 Touch the  button to open the **CONTROL DEFINITION** pop-up window.



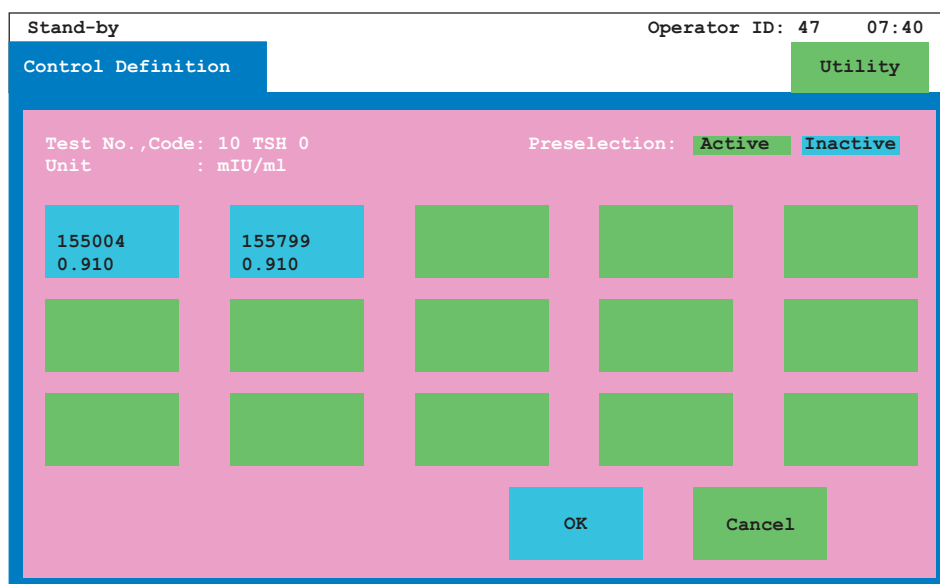
How to...

- 6 Touch the desired control button for which you need to make test selections. The button turns light blue when selected.
- 7 Touch the  button to close the window and open the **CONTROL DEFINITION 2** screen. The available assays for this control are now displayed on the buttons.



Stand-by		Operator ID: 47 07:40				
Control Definition		Utility				
Control no. : 1	Lot no. : 153688	BC Card Scan	Controls			
Control ID : PC U1	Exp. date : 03/2003					
10 TSH 0	21 T4 1	30 FT4 0	40 T-UP 0	50 T3 0	60 FT3 0	100 E2 0
102 E2 2	110 TESTO 0	120 PROG 0	130 PRL 0	140 LH 0	150 FSH 0	160 CORT 0
170 HCGSTAT 0	180 HCG 0	260 DIGIT 0	300 CEA 0	310 AFP 0	380 FERR 0	600 B12 0
610 FOL 0	620 DIGO 0	630 IGE 0	650 INSULIN 0	700 TG 0	740 DHEA-S 0	760 HCG-BETA 0

- 8 Touch the test button which you would like to activate. Up to 15 Lot numbers of the test with the defined target values are now displayed in the **TESTRELATED OVERVIEW** pop-up window for Roche controls. To make changes to the target values, please refer to Chapter 3.10 How to Change a Control Target or Range.



Stand-by		Operator ID: 47 07:40	
Control Definition		Utility	
Test No., Code: 10 TSH 0		Preselection: Active Inactive	
Unit : mIU/ml			
155004 0.910	155799 0.910		
OK		Cancel	

- 9 Touch **Active** in the **Preselection** field (color changes to light blue, inactive button changes to light green) and then the **OK** button. The window closes and returns to the **CONTROL DEFINITION 2** screen. The selected test button is light blue in color. The control/test combination will now be automatically requested.
- 10 Repeat steps 8 and 9 to select further tests for this control.
- 11 Repeat steps 5-9 for all Roche controls that you use.

3.4 How to Define Non-Roche (Non-Bar coded) Controls

Before you can run controls or make manual control selections, you must define your controls.

- 1 Touch the **Utility** tab to open the **UTILITY** screen.
- 2 Touch the **Control Definition** button to open the **CONTROL DEFINITION 1** screen.

- 3 Touch **Controls** button to open the **CONTROL DEFINITION** pop-up window.

- 4 Touch one of the blank buttons on the window and then touch **Add** button to open the **ADD CONTROL** pop-up window.

The Control number defaults to 70. The Control ID defaults to Control G depending on the control number. The control numbers are assigned as follows:

- 1 to 63 reserved for Roche controls
- 64 to 66 Lyphochek 1, 2, 3
- 67 to 69 Liquichek 1, 2, 3
- 70 to 78 freely assignable (Control G to Control O)

To select a different control, enter the corresponding number in the **Control no.** field and press .

- 5 Touch the **Lot no.** field. Type the lot number (max. 8 characters) of the non-Roche control and press .
- 6 Touch the first **Exp.year/month** field. Type the four-digit year of the expiration date of the non-Roche control and press .
- 7 Touch the second **Exp.year/month** field. Type the two-digit month of the expiration date of the non-Roche control and press .
- 8 Touch the button. The **ADD CONTROL** pop-up window closes, the **CONTROL DEFINITION** pop-up window is displayed.
- 9 The button of the control just defined turns to blue. Touch the button.
- 10 All control data is displayed (**Control no.**, **Control ID**, **Lot no.**), all test buttons are blank. The **CONTROL DEFINITIONS DETAIL** pop-up window opens. Touch one of the blank test buttons to assign a test.

The screenshot shows the 'Control Definition' screen with a blue header bar. At the top left, it says 'Stand-by'. At the top right, it shows 'Operator ID: 47' and '07:40'. Below the header, there are two tabs: 'Control Definition' (active) and 'Utility'. The main area is divided into several sections. On the left, there are fields for 'Control no. : 70', 'Lot no. : 197600', and 'Control ID : CONTROL G'. On the right, there are buttons for 'BC Card Scan' and 'Controls'. In the center, a pink pop-up window is displayed with the following fields: 'Test no., code : 10 TSH 0', 'Target value, range : 2.25 25', 'Target lower/upper : 1.69 - 2.81', 'Unit : uIU/ml', and 'Preselection : Active Inactive'. At the bottom of the pop-up are 'OK' and 'Cancel' buttons.

- 11 Touch the **Test no., code** field. Type the test number for the desired test and press . The test code appears automatically next to the number. A list of test numbers can be obtained from the **TEST CONDITIONS** screen (**UTILITY** folder).



You can only select test numbers/codes for assays currently on the reagent disk.

- 12 Touch the first **Target value, range** field. Type the target value (max. 7 characters) for the assay and press .
- 13 Touch the second **Target value, range** field. Type the control range for the assay and press . The control range is a percentage of the target value that is then added or subtracted from the previously entered target value. Example: 25 means that the control range is 25% either side of the target value.
- 14 Touch **Active** in the **Preselection** field (color changes to light blue, inactive button changes to light green). This activates the assay for the control. If you do not activate the assay, the analyzer does not perform that assay on the control when the control is selected.
- 15 Touch . The window closes and returns to the **CONTROL DEFINITION 2** screen.
- 16 Repeat steps 10-15 for assays to be defined on the non-Roche control.

3.5 How to Order a Control for a Particular Reagent Pack (MQR)

You can order an individual control for an individual reagent pack, if necessary.

- 1 Touch the **Inventory** tab.
- 2 Touch the test button for the reagent pack of the test that you want to measure with the control.

Stand-by Operator ID: 47 07:40

Inventory Orders Results QC Status Utility

Reagent Details T4 1 Pos.: 1

No. of tests available : 165

Last lot cal. date (L-Cal) : 03/16/2001

recommended at : 04/15/2001

Last rg. pk cal date (R-Cal) : 03/16/2001

recommended at : 03/23/2001

Assay lot no. : 194389

Reagent pack number : 2873

Lot exp. date : 10/2001

First registration : 03/16/2001 08:44

Manual calib. selection On

Manual control selection On

Close

Water Waste Waste 507

Reagent Scan

- 3 Touch the **Manual control selection On** button, the status changes to **On**, the color changes to light blue. Then touch the **Close** button. All orders for controls for the tests made in the **CONTROL DEFINITION 2** screen (**UTILITY** folder) will be ignored.
- 4 Place the bar coded Roche control in the analyzer. After starting the analyzer the control will be registered by the bar code reader and measured with the reagent pack of the selected test. All other activated tests for this control made in the **CONTROL DEFINITION 2** screen will be ignored.



As long as Manual Quality Control Request (MQR) is **On** for a reagent pack, all controls which contain the corresponding test will only be performed for this test with the selected reagent pack. All the other controls which do not contain this test(s) are performed as normal controls, i.e. for all applicable and selected tests.

3.6 How to Change a Control Target or Range

You can alter the established control ranges of either a Roche or non-Roche control.

- 1 Touch the **Utility** tab to open the **UTILITY** screen.
- 2 Touch the **Control Definition** button to open the **CONTROL DEFINITION 1** screen.

- 3 Touch the **Controls** button to open the **CONTROL DEFINITION** pop-up window.

- 4 Touch the control button for which you need to change control values. The button turns light blue when selected.
- 5 Touch the **OK** button to close the window and open the **CONTROL DEFINITION 2** screen. The available assays for this control are displayed on the buttons.

Stand-by		Operator ID: 47		07:40	
Control Definition			Utility		
Control no. : 1		Lot no. : 153688		BC Card Scan	
Control ID : PC U1		Exp. date : 03/2003		Controls	
10 TSH 0	21 T4 1	30 FT4 0	40 T-UP 0	50 T3 0	60 FT3 0
102 E2 2	110 TESTO 0	120 PROG 0	130 PRL 0	140 LH 0	150 FSH 0
170 HCGSTAT 0	180 HCG 0	260 DIGIT 0	300 CEA 0	310 AFP 0	380 FERR 0
610 FOL 0	620 DIGO 0	630 IGE 0	650 INSULIN 0	700 TG 0	740 DHEA-S 0
					760 HCG-BETA 0

- Touch the test button which requires the altered control values. If the control is a Roche control, proceed with step 7. If the control is a non-Roche control, proceed with step 12.

Roche Controls

Stand-by		Operator ID: 47		07:40	
Control Definition			Utility		
Test No.,Code: 10 TSH 0		Preselection: Active Inactive			
Unit : mIU/ml					
155004 0.910	155799 0.910				
		OK		Cancel	

- The different test lots and target values are displayed in the **TEST RELATED OVERVIEW** pop-up window. Ensure that **Active** is highlighted light blue in the **Preselection** field. Touch the button of the lot whose target values you wish to alter, the **CONTROL DEFINITION DETAILS 1** pop-up window opens.




Stand-by Operator ID: 47 07:40

Control Definition Utility

Control no.: 1 Lot no.: 190599 BC Card Scan Controls

Control ID : PCU1

10 TSH 0	21 T4 1	Test no., Code : 10 TSH 0	3 0	100 E2 0
102 E2 2	110 TESTO	Assay Lot No. : 155004	0 0	160 CORT 0
170 HCGSTAT 0	180 HCG 0	Target value,range : 1.39 25	0 0	600 B12 0
610 FOL 0	620 DIGO	Target lower/upper : 0.973 - 1.81	0 0	760 HCG-BETA 0
		Unit : uIU/ml		
		OK Cancel		

- 8 Touch the first **Target value,range** field. Type the revised target value (max. 7 characters) for the assay and press .
- 9 Touch the second **Target value,range** field. Type the revised range for the assay and press . The control range is a percentage of the target value that is then added or subtracted from the previously entered target value. Example: 25 means that the control range is 25 % either side of the target value.
- 10 Touch the  button to close the pop-up window and return to the **CONTROL DEFINITION 2** screen.
- 11 Repeat steps 6-10 for all assays of Roche controls for which control values need to be changed.



Manual changes have top priority and will not be overwritten by target values on the reagent pack bar code that may be determined at a later date.

Non-Roche Controls




Stand-by Operator ID: 47 07:40

Control Definition Utility

Control no.: 70 Lot no.: 197600 BC Card Scan Controls

Control ID : CONTROL G

		Test no., code : 10 TSH 0		
		Target value,range : 2.25 25		
		Target lower/upper : 1.69 - 2.81		
		Unit : uIU/ml		
		Preselection : Active Inactive		
		OK Cancel		

- 12 Touch the first **Target value,range** field. Type the revised target value (max. 7 characters) for the assay and press .
- 13 Touch the second **Target value,range** field. Type the revised range for the assay and press . The control range is a percentage of the target value that is then added or subtracted from the previously entered target value. Example: 25 means that the control range is 25 % either side of the target value.
- 14 Ensure that **Active** is highlighted light blue in the **Preselection** field.
- 15 Touch the  button. The pop-up window closes, the test button in the **CONTROL DEFINITION 2** screen is highlighted light blue.
- 16 Repeat step 6 and steps 12 to 15 for all assays of non-Roche controls for which control values need to be changed.

3.7 How to Delete a Single Open Request

You can delete single open requests in the **ORDERS** screen. The procedure is the same for both Rack and Disk systems.

- 1 Touch the **Orders** tab to open the **ORDERS** screen.

- 2 If the sample to be deleted has a numeric ID, touch the **Sample ID** field. If the ID is alphanumeric, proceed to step 4.
- 3 Type the sample ID number to be deleted. Press . Proceed to step 5.
- 4 If the sample to be deleted has an alphanumeric ID, touch the **Sequence No.** field. Press or until you find the sample to be deleted.
- 5 While the cursor is in either the **Sample ID** or **Sequence No.** field, press to open the Delete Sample **CONFIRMATION** pop-up window.

- 6 Touch the button to delete the sample.

3.8 How to Delete Open Requests – Disk System

You can delete all samples with open requests in the **STATUS** screen. The samples deleted are only those for the sample disk number currently displayed on the screen.

The analyzer must be in the Stand-by mode before you can delete samples.

- 1 Touch the **Status** tab to open the **STATUS** screen.

The screenshot shows the STATUS screen with the following elements:

- Top bar: Stand-by, Operator ID: 47, 13:00
- Navigation tabs: Inventory, Orders, Results, QC, Status (selected), Utility
- Sample Disk Status section:

1 Compl	2 Compl	3 Compl	4 Compl	5 Compl
6 Compl	7 Compl	8 Compl	9 Compl	10 Compl
11 Compl	12 Incmp	13 Compl	14 Compl	15 Compl
16 Compl	17 Compl	18 Proc	19 Proc	20 Proc
21 Proc	22 Proc	23 Proc	24 Proc	25 Smpl
26 Occup	27 Occup	28 Stop	29 Empty	30 Empty
- Operator ID : 47
- Disk No. : 1
- Last result at : 13:46
- Buttons: Sample Scan, Open Requests

- 2 Touch the **Disk No.** field.
- 3 Type the sample disk number for which requests are to be deleted. Press **Enter**.
- 4 Touch the **Open Requests** button to open the **OPEN REQUESTS** pop-up window.
- 5 Touch the **Delete Open** button to delete open test requests.

The screenshot shows the STATUS screen with the Open Requests pop-up window open. The pop-up window displays:

- Open Requests
- Number of open reqs.: 35
- Buttons: Delete Open, Cancel

The background screen shows the same Sample Disk Status table as before, with the Disk No. field set to 1.



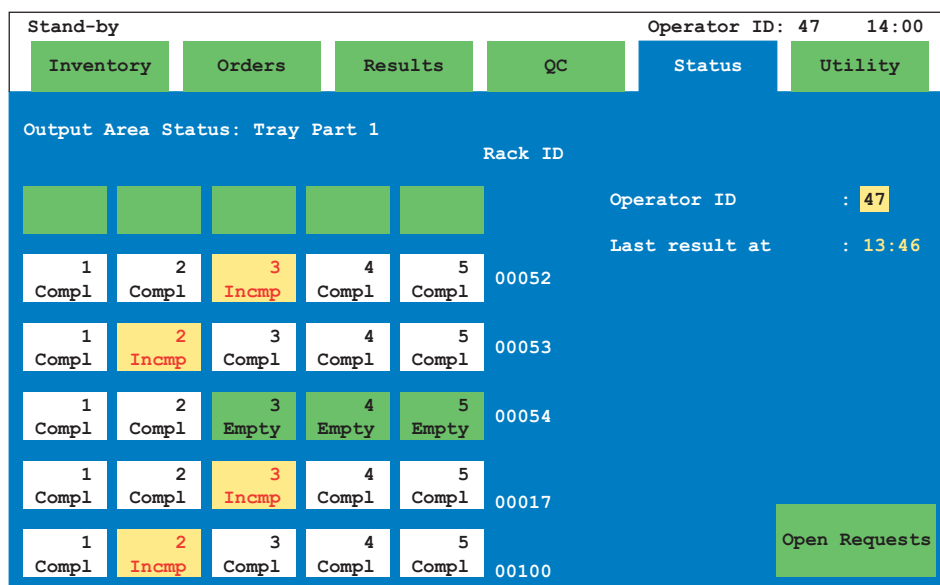
The **STATUS** screen only displays samples that have been assigned a position. To ensure that all open requests have been deleted, repeat steps 2 - 5 for all disk numbers.

3.9 How to Delete Open Requests – Rack System

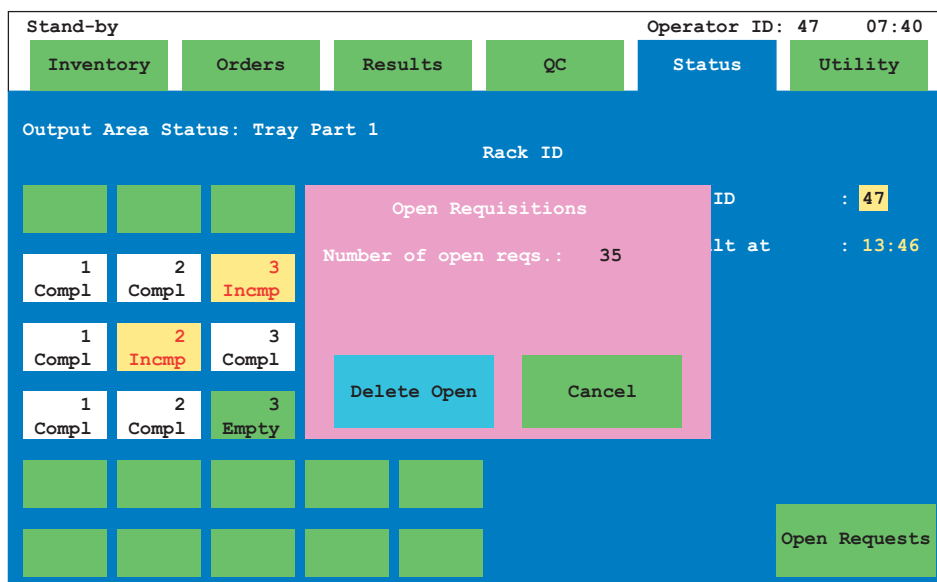
You can delete all samples with open requests in the **STATUS** screen.

The analyzer must be in the Stand-by mode before you can delete samples.

- 1 Touch the **Status** tab to open the **STATUS** screen.



- 2 Touch the **Open Requests** button to open the **OPEN REQUESTS** pop-up window.



- 3 Touch the **Delete Open** button to delete open test requests.

3.10 How to Manually Upload Results

If you have automatic uploading OFF and you are interfaced with a host computer, you must upload sample results manually. Results may be uploaded more than once, if necessary.

The procedure is the same for both Rack and Disk systems.

To upload a **SINGLE** result

- 1 Touch the **Results** tab to open the **RESULTS** screen.

The screenshot shows the 'RESULTS' screen of the software. At the top, there is a status bar with 'Stand-by' on the left and 'Operator ID: 47 15:00' on the right. Below this is a navigation bar with six tabs: 'Inventory', 'Orders', 'Results' (which is highlighted in blue), 'QC', 'Status', and 'Utility'. The main area of the screen has a blue background. It contains several input fields and buttons. On the left, there are three labels: 'Sample ID', 'Sequence No.', and 'Disk - Pos.'. To their right are input fields containing '23456', '1', and '1 - 7' respectively. Further right, there are two buttons: 'Filter Off' and 'Document'. Below these, there is a label 'Samples : 101' and a button 'Delete Doc. Samples'. At the bottom left, there is a small box showing '14:46', 'HCGSTAT 0', and '189'. The bottom of the screen features a grid of five empty green boxes arranged in two rows (two in the first row, three in the second).

- 2 If the sample ID to be uploaded is numeric, touch the **Sample ID** field. If the ID is alphanumeric, proceed to step 4.
- 3 Type the sample ID number to be uploaded. Press . Proceed to step 5.
- 4 If the sample ID to be uploaded is alphanumeric, touch the **Sequence No.** field. Press or until you reach the desired sample ID.
- 5 When the sample is displayed, press to upload the sample result to the host.

To upload **MULTIPLE** results

- 1 Touch the **Results** tab to open the **RESULTS** screen.

Stand-by Operator ID: 47 15:00

Inventory Orders **Results** QC Status Utility

Sample ID : 23456

Sequence No. : 1

Disk - Pos. : 1 - 7

Filter Off Document

Samples : 101 Delete Doc. Samples

14:46
HCGSTAT 0
189

- 2 Touch the **Filter Off** button to verify your filter settings. The results uploaded depends on whether Filtering is **ON** and the selections made in the **FILTER SELECTION** pop-up window. For more detailed information please refer to Chapter 2.14, Results.
- 3 Touch the **Document** button to open the **DOCUMENT SETUP** pop-up window.

Stand-by Operator ID: 47 15:00

Inventory Orders **Results** QC Status Utility

Sample ID : 23456

Sequence No. : 1

Disk - Pos. : 1 - 7

Filter Off Document

Samples : 101 Delete Doc. Samples

14:46
HCGSTAT 0
189

Print/Upload

First Seq. No. : 1

Last Seq. No. : 9999

OK Cancel

- 4 Touch the **First seq. no.** field. Enter the first sequence number in the range of samples to upload. Press **Enter**.
- 5 Touch the **Last seq. no.** field. Enter the last sequence number in the range of samples to upload. Press **Enter**.
- 6 Touch the **OK** button to activate the upload. The results are uploaded to the host.



The word **Documented** appears next to the sequence number after the sample is documented.

3.11 How to Change Expected Values

Expected values and units can be altered in the **TEST CONDITIONS** screen (**UTILITY** folder).

- 1 Touch the **Utility** tab to open the **UTILITY** screen.
- 2 Touch the **Test Conditions** button to open the **TEST CONDITIONS** screen.

Test Code	Expected Value
TSH 0	10
T4 1	21
T3 0	50
HCGSTAT 0	170
CEA 1	301
AFP 1	311
PSA 1	321
FERR 0	380
B12 0	600
FOL 0	610
DIG 0	620

- 3 Touch the test button for which you want to change the expected values or units. The **TEST CONDITIONS DETAILS** pop-up window opens.

Test code : TSH 0 Test no.: 10

Unit: **uIU/ml** mIU/l

Diluent lot no. : 194408 Threshold : 0

Exp. value Lower limit : 0.270 Expected values check: **On** Off

Upper limit : 4.20 Daily calib request : **On** Off

Instrument factor A : 1.00 Diluent factor :

Instrument factor B : 0.000

OK Cancel



- 4 If you need to change the unit of measure in addition to the expected values, touch the desired unit (e.g. nmol/l). The selected unit is highlighted light blue.
- 5 Touch the **OK** button to accept all changes in the window.

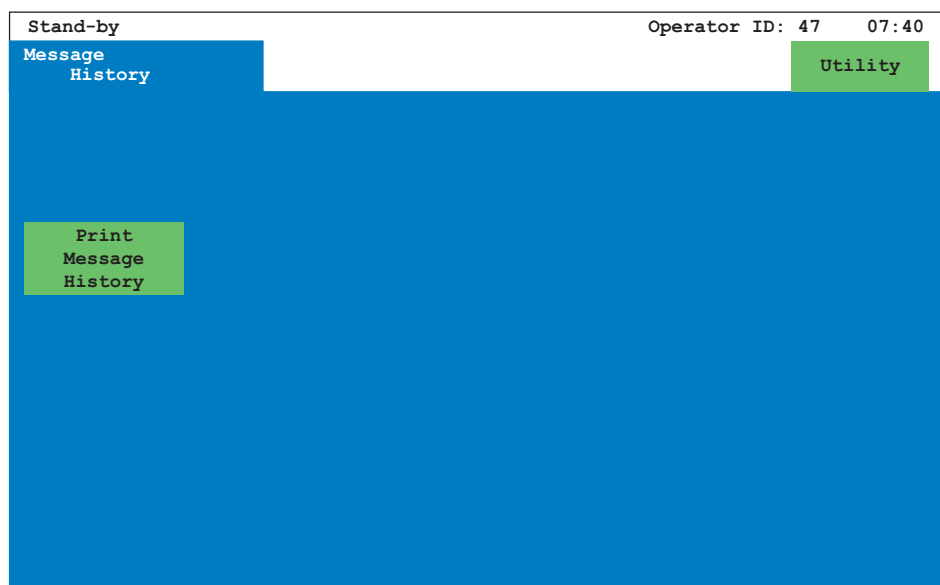


The alterations are not overwritten by the scanning in of a new reagent pack or bar code card.

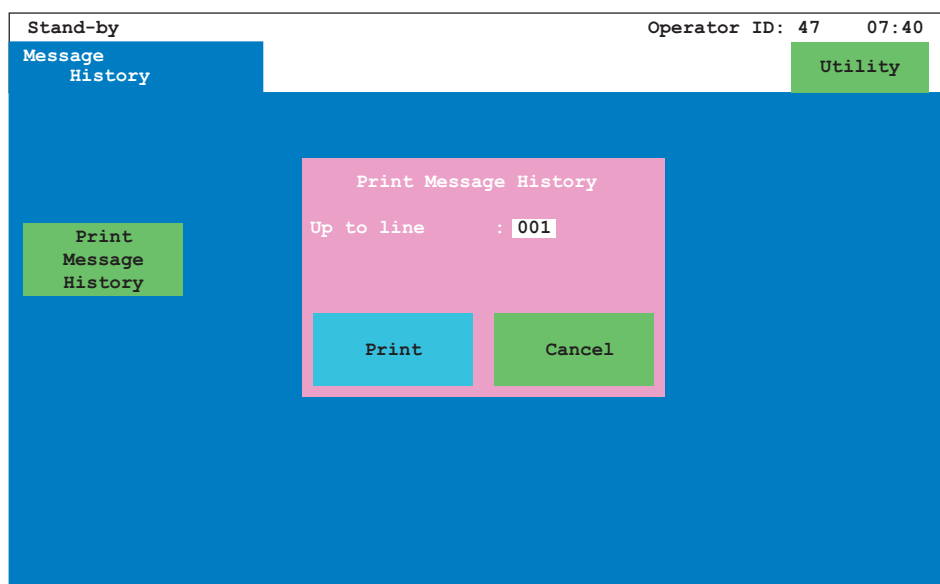
3.12 How to Print Message History



One of the first steps in troubleshooting is to print a message history of the past 10 - 20 alarm messages. A maximum of 200 messages can be saved and printed out. The most recent messages are listed first. If the memory bank is full, the oldest messages are deleted.

- 1 Touch the  tab to open the **UTILITY** screen.
- 2 Touch the  button to open the **MESSAGE HISTORY** screen.



- 3 Touch the  button to open the **PRINT MESSAGE HISTORY** pop-up window.

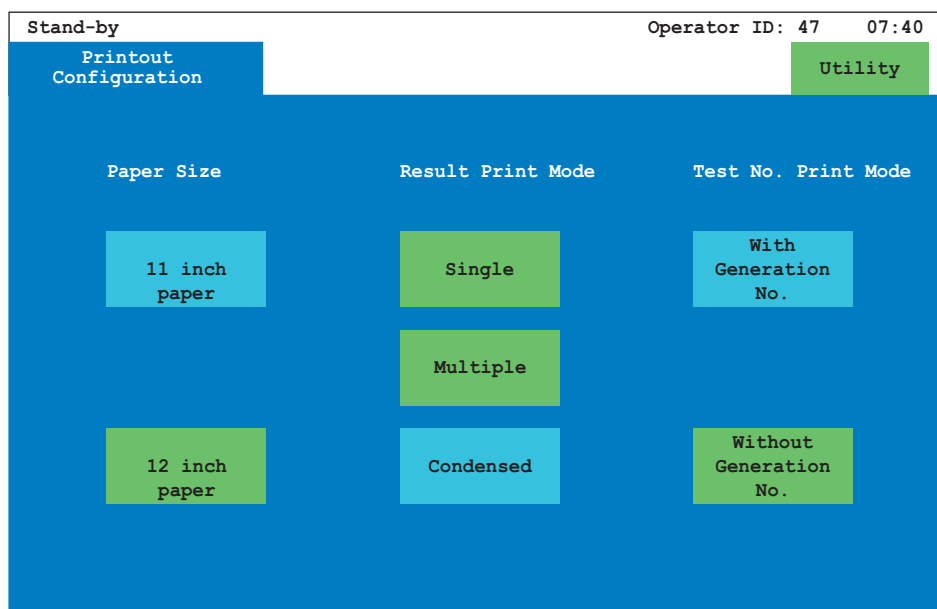


- 4 Touch the **Up to line** field. Type the number of message lines to print. Press . An average number of lines to print is 10 - 20.
- 5 Touch the  button to initiate the report print out.

3.13 How to Change Printout Configuration

In the **PRINTOUT CONFIGURATION** screen (**UTILITY** folder), you can regulate the form the printout of results will take.

- 1 To select the desired printout configuration, touch the **Utility** tab to access the **UTILITY** screen.
- 2 Touch the **Printout Configuration** button to open the **PRINTOUT CONFIGURATION** screen.



- 3 Touch the appropriate buttons to regulate the form of the printout.

Button

11 inch paper

12 inch paper

Single

Multiple

Condensed

With generation No.

Without generation No.

Meaning

Continuous-form paper 11 inch

Continuous-form paper 12 inch

Results of a single sample per page

Results of multiple samples per page

Highly compressed printout of results

With test generation numbers

Without test generation numbers

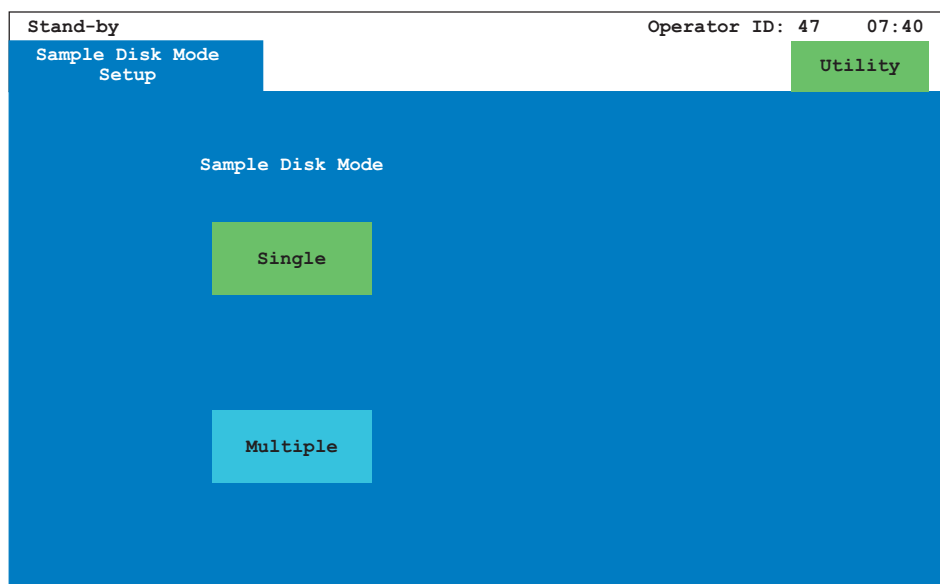
3.14 How to Change the Sample Disk Mode

Single disk or multiple disk modes are available on the Elecsys 2010.

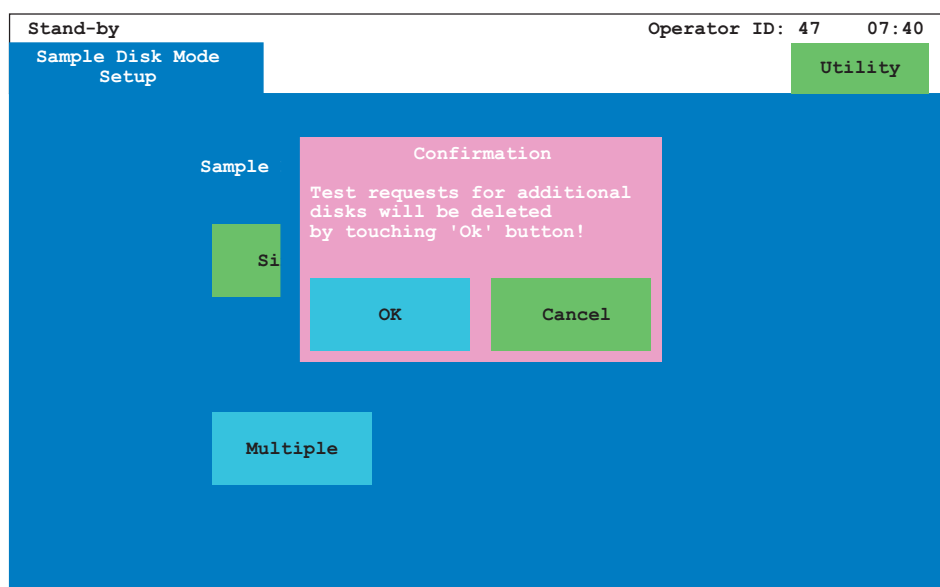


Alterations to the disk mode should only be carried out when the analyzer is in Stand-by. All open requests should be completed before making any changes, otherwise they will be deleted.

- 1 Touch the **Utility** tab to open the **UTILITY** screen.
- 2 Touch the **S. Disk Mode Setup** button to open the **SAMPLE DISK MODE SETUP** screen.



- 3 Select the mode in which you wish to work by touching either the **Single** or **Multiple** button. The **CONFIRMATION** pop-up window opens.
- 4 Touch the **OK** button to confirm the selected disk mode. All open requests will be deleted.



Glossary

Numbers

2-dimensional bar code (2D) type of bar code found on the reagent pack, calibrator and control bar code cards. Utilizes PDF417 symbology. This bar code contains more information than traditional linear bar codes.

A

A-Line the unit of the rack sampler where you load the tray and sample racks.

adequate sample volume the amount of sample remaining in the sample container after all assays have been pipetted is greater than or equal to the recommended dead volume for the container.

analytical sensitivity the lower detection limit (LDL) of the assay. The analytical sensitivity represents the lowest analyte concentration that can be distinguished from zero. It is calculated as the concentration two standard deviations above the lowest standard used in the master calibration. Since the master calibration is performed by Roche Diagnostics, it is not possible for the customer to verify the sensitivity exactly as it was performed at Roche Diagnostics. CalSet vial 1 was not used to determine analytical sensitivity. Master calibration standards were used.

analyzer unit the analyzer unit consists of the sample/reagent area, consumables area, measuring area and power switch.

AOX adsorbable organic halogens.

aspiration station position located next to the incubator where the assay cup containing reaction mixture is placed for aspiration into the measuring cell by the sipper probe.

assay

- a specific test.
- the process of measuring a substance.

assay cup (or cup) clear plastic cup that is used to hold the assay reaction mixture. Cups are configured in trays that contain 60 cups each.

assay tip (or tip) disposable pipette tip made of black, conductive plastic. Assay tips are used by the sample/reagent (S/R) probe. Tips are configured in trays that contain 120 tips each.


assigned values the assigned value for a calibrator (Cal 1 or Cal 2) is encoded on the calibrator bar code card.


B

B-Line transports sample racks, single file, first to the rack bar code reader and then to the sampling position.

bar code a series of lines representing data encoded in a format containing information that can be automatically scanned. Bar codes used on the analyzer can either be linear or 2D.

bar code card either a calibrator or control card. These cards contain either all assigned values (calibrator card) or target values and ranges (control card) for assays.

 bar code card reading station slot located between the sample disk and the reagent disk where the calibrator or control bar code cards are scanned.



 bar code card reading station slot located to the back left of the reagent disk where the calibrator or control bar code cards are scanned.

bar code reader the device that reads the code from a sample, reagent bar code label or bar code card.

bar code scan	process to read the bar code information into instrument memory. Three are possible: reagent scan, sample scan (disk system only) and bar code card scan.
BC card scan	a scan to read the information from the 2D calibrator bar code card or control bar code card.
BCR	Abbreviation for bar code reader.
BlankCell	reagent pack used to perform an initial BlankCell procedure. This procedure is primarily done by RD Service.
block	a result can be blocked by the operator (B) or the system (S). A blocked result is printed or uploaded to the host with the appropriate flag (i.e., "B" or "S"). Block a result that is questionable and that should be repeated.
bottle set 1	the set of ProCell/CleanCell that occupies positions 1 and 2 in the system reagent compartment.
bottle set 2	the set of ProCell/CleanCell that occupies positions 3 and 4 in the system reagent compartment. When starting from Stand-by, the analyzer always accesses bottle set 2 first.
bound/free separation	the physical separation of reagent and/or sample which is bound to a solid phase (i.e., microparticles) from free reagent and/or sample. This step occurs in the measuring cell.
bridging principle	one of three test principles available on the 2010 analyzer. It is used to detect antibodies in the sample (e.g., IgG, IgM or IgA).
button	buttons are found on the screen or pop-up window. They can be touched to either initiate an action or move to a different screen. Buttons found on a screen are "screen buttons" and buttons found on a pop-up window are "window buttons".

C

C-Line	receives racks from the B-Line. It holds a maximum of 15 racks at a time.
calibration	the process to standardize the instrument with samples of known concentration. This process establishes factors and or updates baselines to enable conversion of the response of the instrument to concentration (or activity) for the constituent being measured.
calibration factor	one of the six calibration quality criteria used to determine the outcome of a calibration. This criterion is only used in determining R-Cals. It is derived by the comparison of two different calibrations. A factor of 1.0 is produced if the two calibration are perfectly matched. Each R-Cal is compared to the L-Cal to generate this factor. A successful calibration should have a factor of 0.8 - 1.2. The remaining criteria are missing values, monotony of curve, minimum signal, deviation of duplicate measurements and system errors.
calibration frequency	the specified interval at which an assay must be calibrated. This frequency is found in reagent package inserts.
calibration function	the type of calibration (e.g., Rodbard function, linear function, cutoff function).
calibration quality criteria	criteria applied to the automatic validation of every calibration on the analyzer.
calibration type	lot calibration (L-Cal) or reagent pack calibration (R-Cal)

calibration validation	procedure performed by the analyzer software whereby a calibration data set is checked versus specific criteria encoded in the reagent bar code. The conclusion of a validation is a green (successful), yellow (questionable) or red (failed) calibration.
calibration verification	a procedure required by HCFA and CLIA. "Calibration verification is the assaying of calibration materials in the same manner as patient samples to confirm that the calibration of the instrument kit or test system has remained stable throughout the laboratory's reportable range for patient test results". ¹
calibrator	a substance with known concentrations used in the calibration of immunoassays.
capacitance	used in liquid level detection in the S/R probe and sipper probes. The probes carry a high frequency low voltage electrical charge. The frequency and electrical charge characteristics are altered and sensed when the probe touches liquid.
CapTwist	opener to aid in the manual removal of ProCell and CleanCell bottle caps.
circuit breaker	found on the lower right side of the analyzer. It controls power to the peltiers, thereby controlling the temperature in the reagent disk, incubator, system reagent compartment and measuring cell.
CleanCell	reagent used to: <ul style="list-style-type: none"> ● cleanse the tubing system and measuring cell after each measurement ● condition the electrodes.
Clean-Liner	disposable liner used in the solid waste tray. Clean-Liner has a sliding lid that can be closed to prevent spillage of potentially biohazardous material from used tips and cups.
clot detection	used in the aspiration systems of the S/R probe. As the appropriate volume of sample is aspirated, the release of vacuum is monitored by a vacuum/pressure transducer. If an abnormal vacuum is detected, a clot detection alarm is issued to notify you and the sample is not aspirated.
competitive principle	one of three test principles available on the 2010 analyzer. It is used to detect analytes of low molecular weight (e.g., FT3).
 compl	a sample status found on the STATUS screen. The sample is complete and can be removed from the sample disk. This status is not seen for calibrators.
 compl	a sample status found on the STATUS screen. The sample is complete and be removed from the sample rack on the C-Line.
consumables	items that are used during test processing and must be replaced on a regular basis by the operator (i.e., assay cups and tips, printer paper, etc.).
consumables area	consists of three assay cup trays, three tip trays, gripper, incubator, cup disposal opening, pipetting station, liquid waste container, distilled water container and solid waste tray and liner.
container	See sample container.
continuous access	ability of the operator to access the sample disk to load samples at any time during operation or to place racks on the A-Line at any time during operation.
control (or quality control)	a substance with known values of analytes used to verify calibration and performance of immunoassays.

¹ 42 United States Code of Federal Regulations. Part 493.1217. Standard; Calibration and calibration verification procedures.

control ID	the abbreviated control name found in the software (e.g., PC U1 or PC TSH).
control name	the name of a control (e.g., PreciControl Universal).
control unit	the part of hardware that consists of the touchscreen monitor, keyboard and floppy disk drive.
cup	See assay cup.
cup disposal opening	opening to the left of the incubator where used assay cups are disposed into the solid waste tray.
cycle	instrument time interval of 42 seconds.

D

data disk	contains files necessary for the analyzer and the software to work together. These files include: <ul style="list-style-type: none"> ● analyzer specific adjustment files ● assay reference tables ● calibration data ● up to 600 orders and test results.
data entry field	a field on the software screen where you can enter or edit information. This field is touch-activated.
data field	a field on the software screen that contains information only. There is no user access. This field cannot be activated.
dead volume	the amount of sample that must remain in the container after sample aspiration.
detection unit	contains the photomultiplier tube, peltier, flow-through measuring cell, magnet drive assembly and an amplifier circuit board. The detection unit is the core of the 2010 analyzer.
deviation of duplicate	one of the six calibration quality criteria. For a calibration to measurements be successful, replicate measurements must fall within a specific duplicate limit. The remaining criteria are missing values, monotony of curve, calibration factor, minimum signal and system errors.
diluent	See Universal diluent.
dilution factor	a software preset dilution ratio that is used by the analyzer to automatically perform a requested dilution. Dilutions may be 1:2, 1:5, 1:10, 1:20, 1:50 and 1:100. Recommended dilution factors are found in reagent package inserts and in product informations.
disk position	a position on either the sample or reagent disk. There are up to 30 sample disk positions. There are up to 18 reagent disk positions.
dispense	delivery of a sample or reagent by the appropriate probe to an assay cup.
DNA/RNA probe	a test principle that can be used on the 2010 analyzer. The DNA/RNA probe is for the detection of DNA or RNA molecules and is currently under development.
document	the process of printing, uploading or printing AND uploading a report for a sample which in turn transfers the sample results to the RESULTS screen.
door	See front access panel.
download	the transfer of information (e.g., sample ID, test requests) from the host computer system to the 2010 analyzer.







E

ECL	electrochemiluminescence. The detection technology used on Elecsys immunoassay analyzers.
empty	a sample status found on the STATUS screen. An empty sample disk or rack position exists.
error handling	process during which the analyzer attempts to recover from an error condition (e.g., a tip was not picked up from a tray). If the analyzer cannot successfully recover from the error, an alarm is issued.
expected values	the values for an assay that should be recovered for a "normal" result. Also known as normal range or reference range.
extended dynamic range	the measuring range for an assay at its highest dilution.

F

filter	a means of sorting samples that you want to view, document or print. You can filter by "Samples", "Type" or "Document" on the RESULTS screen.
first registration date	the date that the reagent pack was first successfully scanned by the bar code reader. This date is found in the assay REAGENT DETAILS pop-up window.
flag	an identifier used to call attention to a result. Flags are seen in conjunction with data alarms.
floppy disk	(FD) a small plastic disk coated with magnetic material on which data from a computer can be stored.
floppy disk drive	holds the data disk required for operation. The drive is located behind the front access door above the solid waste tray.
front access panel (or door)	door behind which the floppy disk drive and solid waste tray reside.
functional sensitivity	concentration at which a particular level of imprecision is obtained.

G

global action keys	keys that are found on the keyboard that remain active on all screens. These buttons include:  ,  ,  ,  ,  and  .
gripper	a unit that moves in three directions (X, Y and Z). It is equipped with a mechanism that picks up tips or cups from the tray. The gripper picks up tips/cups and transports them to/from the incubator, aspiration station or cup disposal opening.

H

host communication	information exchange with a laboratory information system (host computer).
--------------------	--

I

incmp	a sample status found on the STATUS screen. There was an error during processing, or the sample has a result greater than the measuring range. This status is not seen for calibrators.
incubator	an aluminum block maintained at 37 °C that accommodates 32 assay cups containing reaction mixture.
Initial BlankCell procedure	procedure performed by RD Service and utilized to maintain the sensitivity of the measuring cell and photomultiplier tube.

input buffer	the buffer zone between the A-Line and the B-Line. It holds a maximum of five racks.
instrument alarms	displayed alarms that indicate abnormal instrument conditions (i.e., reagent disk temperature, mechanical malfunctions, etc.).
inventory control	real time monitoring of the actual amount of all consumable items on the analyzer.

L

Laboratory Information data System	(LIS) external computer with appropriate software for management (host computer)
Laboratory System Manager	(LSM) a common user interface for patient administration, sample ordering, validation and quality control in clinical chemistry and immunology.
linear bar code	a traditional 1D bar code. It has limited data capacity.
liquid level detection	(LLD) ability of the sample/reagent and sipper probes to sense liquid.
liquid waste container	contains liquid waste generated by the analyzer. The four liter plastic bottle is located in the front of the ProCell and CleanCell reagent compartments.
lot calibration	(L-Cal) a calibration performed with a fresh reagent pack that has been on the analyzer less than 24 hours. The lot calibration is valid for all other reagent packs of the same lot, provided these reagent packs were stored as specified in the package insert and not on the analyzer longer than seven days.
lower detection limit	(LDL) See analytical sensitivity.

M

master calibration	A reference standardization curve utilizing master test kit reagents and certified reference standard material [e.g., World Health Organization (WHO) reference material] measured at Roche Diagnostics. This curve uses 10 to 12 points. The reference standard curve is the basis for the production of master calibrators.
master curve	A lot-specific master calibration curve (n=5 or 6) measured at Roche Diagnostics using lot-specific test kit reagents and master calibrators. The shape of the lot-specific master curve is characterized by a four-parameter Rodbard function. The data characterizing this curve is stored in the lot-specific reagent bar code. Lot-specific calibrator assigned values (i.e., CalSet assigned values) are read from the lot-specific master calibration curve and encoded in the CalSet calibrator bar code card.
Material Safety Data Sheets	(MSDS) documents that list components of chemical solutions and precautions for the handling and disposal of the solutions.
mean	the average value of a set of numbers, used in quality control evaluations.
measuring cell	flow-through cell where result measurement takes place. The measuring cell is part of the detection unit.
measuring range	See reportable range.
microparticle	paramagnetic streptavidin-coated microparticles are the solid phase used in the bound/free separation step of ECL.
microparticle mixer	paddle on the sample/reagent arm that thoroughly mixes the microparticle reagent to ensure resuspension prior to use.

minimum signal	one of the six calibration quality criteria. Each calibrator replicate value must be greater than a designated minimum signal value for a successful calibration. The remaining criteria are missing values, monotony of curve, calibration factor, deviation of duplicate measurements and system errors.
missing values	one of the six calibration quality criteria. No calibrator replicates may be missing for a successful calibration. The remaining criteria are monotony of curve, calibration factor, minimum signal, deviation of duplicate measurements and system errors.
monotony of curve	one of the six calibration quality criteria. All measured calibrator values must fall in either ascending (sandwich or bridging principle) or descending (competition principle) order for a successful calibration. The remaining criteria are missing values, calibration factor, minimum signal, deviation of duplicate measurements and system errors.

N

normal range	See expected values.
note	<ul style="list-style-type: none"> ● a statement in the text called out to make the operator aware of specific information. ● a result message that is displayed if a predefined result condition exist. These message are set in the software and are not user-definable (i.e., "reac.", "n-reac." and "border").

O

occup	a sample status found on the STATUS screen. The sample disk position or rack position is occupied.
open request	orders for a sample that have not yet been performed.
operation	an instrument status condition that occurs when the analyzer is performing its routine operations.
operation ON/OFF switch	found on the front left of the analyzer. This switch is used to turn the analyzer ON or OFF.
operator ID	a number used to identify different operators.
order (or request)	tests selected for a specific sample or control.
output buffer	the buffer zone between the B-Line and the C-Line. It holds a maximum of 5 racks.

P

paramagnetic	used in reference to microparticles. Microparticles themselves do not exhibit magnetic properties, but are capable of becoming magnetic when in the presence of a magnet or magnetic field.
parameters	a set of criteria used to establish how an assay is performed. All parameters are encoded on the reagent bar code label and cannot be changed by the operator.
pending requests	partial results for a sample are available; while other tests have not yet been performed or completed.
photomultiplier	a photoemissive photoelectric tube that amplifies emitted photons from the ECL reaction and converts them into an electric signal.

photon	a quantum of electromagnetic energy having both particle and wave behavior. It has no charge or mass, but possesses momentum; it carries the light emitted from the ECL reaction.
pipetting station	located to the upper left of the incubator. Cups and tips are moved by the gripper to this location for sample and reagent pipetting, sample dilution or sample pretreatment.
pop-up window	a window containing additional information that “pops up” within existing screens. It may appear as a result of touching a button on a screen.
positive displacement	water in the pipettor that is displaced by the plunger during an aspirate/dispense cycle. Is equal to the amount of sample/reagent that is aspirated/dispensed by the probe.
proc	a sample status found on the STATUS screen. The sample is in process (i.e., all assays have been pipetted), but results are not ready.
ProCell	reagent used to: <ul style="list-style-type: none"> ● condition the electrode ● transport the assay reaction mixture ● wash the streptavidin-coated microparticles ● generate signal.

Q

QC chart	an assay/control combination. Up to 60 charts per control are stored in the QC screen.
qualitative assay	a determination of a substance without regard to quantity.
quality control	See control.
quantitative assay	a determination of a substance with regard to a specified number or amount.
questionable calibration	a calibration that does not successfully pass the calibration quality criteria. The curve may be manually released or rejected by the operator.

R

rack	a device that holds sample cups or primary sample tubes. Each rack holds a maximum of five samples. Racks are transported on the lines of the rack sampler.
rack bar code reader	auto-discriminating reader that reads both sample bar code labels and the rack ID bar code.
rack circuit breaker	located on the left side of the rack sampler. It controls power to the rack sampler unit. It should be left ON.
rack ID	the bar code on the end of the rack that identifies the rack for positive sample ID.
rack pusher arm	arms located on the A-Line, B-Line and C-Line. They push the racks along the respective line.
rack sampler	unit consisting of an A-Line for rack input, B-Line for transport and sampling and a C-Line for rack receipt.
reaction mixture	sample combined with reagents in the assay cup. This final mixture is aspirated into the measuring cell.
reagent cap open/close	a mechanism that automatically opens and closes the remechanism agent caps before and after reagent pipetting. This controls reagent evaporation.

reagent disk	disk where reagent packs are located while on the analyzer. The disk contains 18 positions in total.
reagent disk cover	the cover that closes the reagent disk compartment. This cover assists in controlling the temperature of the reagent disk.
reagent disk position	one of 18 positions on the reagent disk. Its presence is monitored by a sensor.
reagent pack	reagent used on the Elecsys analyzer. It is composed of three physically connected bottles (R1, R2 and Microparticles). The components of a reagent pack cannot be interchanged with another reagent pack.
reagent pack calibration	(R-Cal) a reagent pack calibration is performed when reagent has been on board the analyzer more than 24 hours or when generated by an operator-released calibration. A reagent pack calibration is valid for one specific reagent pack only. The reagent pack calibration is compared to the most recent stored L-Cal for validation.
reagent pack number	the unique number on the reagent bottle label that identifies each reagent pack.
reagent scan	a scan of the reagent disk to read information from the 2D reagent bar code into the analyzer and update inventory.
real time	display of information on the monitor at the moment a change altering such information occurs.
renewed calibration	a calibration that is performed when the assay-specific time has expired. Refer to the Calibrators section of the package insert or product information for the assay specific time.
reportable range	the range of results that can be reported for the assay. It is from the lower detection limit to the maximum of the master calibration curve.
request (or order)	tests selected for a specific sample or control.
result	signal converted into concentration for the assay selected. A result is generated for each test performed.
rinse station	rinses the assay tip, mixer or probe externally with deionized water. A separate rinse station exists for the sample/reagent probe and mixer, and for the sipper probe.
Rodbard function	a calibration function used by the analyzer to convert measured signals into concentrations. It utilizes four parameters; two of which define the shape of the curve and the other two define the position of curve.
ruthenium	a rare metallic chemical element of the platinum group that is utilized in electrochemiluminescent reactions.
ruthenium complex	[Ru(byp) ₃ ²⁺] N-hydroxysuccinimide (NHS) ester. The complex is used for the development of light in ECL reactions.

S

sample container	a sample cup or primary or secondary collection tube.
sample disk	has 30 positions for samples, calibrator and controls. Built in adapters allow intermixing of different size primary sample tubes.
sample disk position	one of 30 available positions on the sample disk.
sample ID	the identifier for the sample. It may be up to 22 characters (alphanumeric).
sample rack	See rack.
Sample/Reagent arm	(S/R arm) the horizontal moving arm that holds the sample/reagent probe and microparticle mixer.

Sample/Reagent pipettor	(S/R pipettor) located on the back right of the analyzer. It is filled with deionized water and uses positive displacement to aspirate and dispense from the sample/reagent probe.
Sample/Reagent probe	(S/R probe) mounted on the sample/reagent arm, it uses disposable tips to control carryover, and has liquid level and clot detection for accurate pipetting.
sample scan	a scan of the sample disk to read the information from the primary sample tubes into the analyzer to update the ORDERS screen.
sandwich principle	one of three test principles available on the 2010 analyzer. It is used to detect higher molecular weight analytes (e.g., TSH).
scan	See bar code scan.
screen button	a button in the software that is found on a screen (e.g., ORDERS, MAINTENANCE).
SD	standard deviation, statistic used as a measure of the dispersion or variation in a distribution, equal to the square root of the arithmetic mean of the squares of the deviations from the arithmetic mean.
S.DISK	Abbreviation for sample disk.
select	to mark an item so that a subsequent action can be performed on that item. An item is selected by touching it on the screen.
sequence number	a number from 1 to 9999. This number is automatically assigned to each sample by the analyzer and is used to track orders.
signal	the emission of light converted into an electric signal, which is in turn converted into an analyte concentration. This value can be viewed if activated by service.
sipper arm	horizontally moving arm that holds the sipper probe.
sipper pipettor	located directly to the right of the sample/reagent pipettor. It is filled with deionized water and uses positive displacement to aspirate and dispense from the sipper probe.
sipper probe	probe that aspirates reaction mixture into the measuring cell. This probe also aspirates ProCell and CleanCell.
smpl	a sample status found on the STATUS screen. The sample currently being pipetted.
solid waste tray	metal waste container holding a liner (Clean-Liner) located behind the front access door. Used cups and tips are discarded here during operation.
S/R arm	See Sample/Reagent arm.
S/R pipettor	See Sample/Reagent pipettor.
S/R probe	See Sample/Reagent probe.
standard	traceable reference material solutions used to create the master calibration curve.
Stand-by	status condition that exists when the analyzer is not performing any operations.
STAT position	located at the front of the analyzer. It is an extension of the B-Line. A rack placed here is sampled after the current rack is finished.
STAT sample	(Short Turn Around Time) a sample that requires rapid turnaround. Designated by a yellow button on the STATUS screen.

status	<ul style="list-style-type: none"> ● one of many instrument status conditions ● one of eight sample statuses (i.e., empty, occup, smpl, proc, incmp, remov, compl and stop).
status line	line at the top of the touchscreen that displays the operator ID, system status (i.e., current operating conditions) and actual time. If an alarm occurs, the line changes color depending upon the severity of the alarm.
stop	a sample status found on the STATUS screen. The Stop bar code was scanned.
Stop bar code	a bar code used on the disk system to halt sample scanning.
system errors	one of the six calibration quality criteria. A hardware error occurred during a calibrator measurement. The remaining criteria are monotony of curve, calibration factor, minimum signal, missing values and deviation of duplicate measurements.
system water container	contains the system water supply for the analyzer. The three liter plastic bottle is located in front of the pipettors and to the right of the liquid waste container.

T

target range	the specified limits of a control range for an assay.
target value	the mean value of the control target range for the assay.
temperature controlled	the temperature in a compartment is held stable within a specified range. The temperature is controlled with peltier units.
test	See assay.
test code	the abbreviated name for a test. This code appears on the test buttons within the software.
test principle	a principle used to detect analytes on the analyzer. These include competition, sandwich, bridging and DNA/RNA probe.
test protocol	an exact sequence of test steps used to perform an assay. These test steps include pipetting sample, reagent, incubating the reaction mixture for a specified time, etc.
tip	See assay tip.
tip eject station	position 6 on the pipetting station. This is where the assay tips are ejected from the sample/reagent probe.
touchscreen	LCD screen located on the left side of the analyzer that displays the software. Certain actions are performed by touching buttons on the screen.
tray	a device that holds a maximum of 15 sample racks. Trays are placed on the A-Line or C-Line.
tray indication light	a light at the left side of both the A-Line and C-Line. When the light is green, you can add racks or a new tray to the A-Line, or remove a tray from the C-Line. If red, the pusher arm is about to move; do not remove a tray.
tripropylamine	(TPA) one of two electrochemically active substances used in the ECL reaction. TPA acts with the ruthenium complex to initiate the light generating cycle, which results in the emission of a photon.

U

unit of measure	assays are measured in certain concentration units. The analyzer has designated units of measure for the analytes; this information is contained in the reagent bar code.
universal diluent	reagent used to dilute samples that exceed the reportable range of the assay.
upload	the sending of information (e.g., sample ID, test results, etc.) from the analyzer to the host computer.

W

warning	a statement called out in this manual to make the operator aware of conditions that could cause damage to the analyzer or could cause personal injury.
waste	anything discarded by the analyzer. It could be liquid waste or solid waste (tips and cups).
window button	a button on the software that is found on a pop-up window (e.g., REAGENT DETAILS or SYSTEM RESET).
work list	a report generated from the ORDERS screen. It lists calibrators, controls and samples currently loaded on the sample disk, or programmed on sample racks, as well as the tests selected.

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TG = Tutorial Guide
UG = User's Guide

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